The Health of Biomedical Research Institutions: Report of the Regional Meetings

Proceedings of the
57th Meeting of the
Advisory Committee to the Director, NIH

June 27-28, 1988

U.S. Department of Health and Human Services
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AGENDA

57th Meeting of the Advisory Committee to the Director, NIH

June 27-28, 1988

Building 31C, Conference Room 10
National Institutes of Health
Bethesda, Maryland

THE HEALTH OF BIOMEDICAL RESEARCH INSTITUTIONS: REPORT OF THE REGIONAL MEETINGS

Monday, June 27, 1988

MORNING SESSION

8:30	Opening Remarks Status of Followup Activities to the 56th Meeting of the Advisory Committee to the Director, NIH: "The Role of Biomedical Research in Combating AIDS"	Dr. Wyngaarden
8:45	History and Results of Regional Meetings of the Advisory Committee to the Director, NIH	Dr. Wyngaarden
9:00	Report of the Working Group on Peer Review	Dr. Lenfant
	Discussant	Dr. Healy
10:30	**COFFEE BREAK**	
10:45	Report of the Working Group on Research Resources	Dr. Pickett
	Discussant	Dr. Bock
12:00	**LUNCH**	

AFTERNOON SESSION

1:00	Report of the Working Group on Research Facilities	Dr. Moskowitz
	Discussant	Dr. Korn

2:00	Report of the Working Group on Animal Research Issues	Dr. Whitney
	Discussant	Dr. Guyton
	Discussant	Dr. Glosser
3:00	**COFFEE BREAK**	
3:15	Report of the Working Group on Flexibility and Continuity of Research Funding	Dr. Lenfant
	Discussant	Dr. Healy
4:15	Report of the Working Group on Indirect Costs	Mr. McManus
	Discussant	Dr. Pings
5:00	Adjournment	

Tuesday, June 28, 1988

MORNING SESSION

8:30	Report of the Working Group on Minorities in Biomedical Research	Dr. Kirschstein
	Discussant	Dr. Satcher
10:00	**COFFEE BREAK**	
10:15	Report of the Working Group on Training and Career Development	Dr. Bick
	Discussant	Dr. Brokaw
	Discussant	Dr. Schmid
12:00	Closing Remarks	Dr. Wyngaarden

FOREWORD

At the June 15-17, 1987, meeting of the Advisory Committee to the Director, NIH, discussion was initiated on the health of biomedical research institutions with the aim of examining both the general characteristics and the specific elements of the current Federal system of sponsored research that are contributing to stability or instability of biomedical research institutions and influencing the quality, creativity, and scientific productivity of the biomedical research enterprise. In an effort to extend and intensify those deliberations, a series of regional public meetings was conducted under the auspices of the Advisory Committee to the Director, NIH on that same topic. The meetings were held during the period of November 1987 to March 1988 at seven biomedical research institutions located in a range of geographic areas selected to facilitate the participation of representatives from across the entire country.

The purpose of the Regional Meetings was two-fold: (1) to provide current information concerning the activities of the NIH by describing the broad political context in which the NIH operates; discussing the Federal budget process as it affects the formulation of the NIH budget; demonstrating recent trends in the funding of NIH programs; discussing the broad strategies adopted by the NIH to meet emerging needs; and describing new NIH policies and programs designed to achieve program objectives; and (2) to solicit through public testimony the views of biomedical researchers, university faculty and administrators, representatives of professional societies, and other interested parties concerning the impact of the Federal system of sponsored research on the health of biomedical research institutions.

It was gratifying to note the enthusiasm with which members of the scientific community and professional organizations accepted the invitation of NIH to engage in a frank exchange of views concerning a range of issues that influence the formulation of future policies and the establishment of priorities among the many competing demands on the NIH budget. During the course of the meetings, testimony was received from over 200 individuals, representing a diverse group that included postdoctoral fellows, principal investigators, department chairmen, deans of medical and dental schools, heads of private firms, and officers and representatives of professional societies and voluntary health organizations.

Reports on the regional meetings were presented at the June 27-28 meeting of the Advisory Committee to the Director, NIH, and served to set the stage for discussion of the policy implications of the results of these regional meetings. The following is an account of those deliberations.

James B. Wyngaarden

James B. Wyngaarden, M.D.
Director
National Institutes of Health

Proceedings of the
57th Meeting of the Advisory Committee to the Director, NIH

June 27-28, 1988

THE HEALTH OF BIOMEDICAL RESEARCH INSTITUTIONS

DAY ONE: JUNE 27 MORNING SESSION

Opening Remarks

Status of Followup Activities to the 56th Meeting of the Advisory Committee to the Director, NIH: "The Role of Biomedical Research in Combating AIDS"

James B. Wyngaarden, M.D.
Director
National Institutes of Health

New members of the Advisory Committee were welcomed: Mr. Peter Preuss, Dr. Peter von Hippel, and Dr. Helen Grace. The following Committee members who were attending their last meeting were thanked: Dr. John Bishop, Dr. Arthur Guyton, Dr. David Kipnis, Dr. Carol Newton, and Dr. John Urquhart. Members of the Advisory Council who were attending their first meeting with the Committee were also acknowledged: Dr. Mary Amdur, Dr. Charles Bluestone, Dr. James Boyer, Dr. John Flynn, Dr. Doris Howell, Dr. William McHugh, Dr. Palmer Taylor, Dr. Joseph Warshaw, and Dr. Hans Weill. (See rosters in appendix for members' affiliations.)

Since the Committee's last meeting, several steps have been taken to strengthen the NIH AIDS research program. An Office of AIDS Research has been established within the Office of the Director to act as a focal point to coordinate the NIH AIDS research effort, centralize various AIDS-related policy functions, and represent the Director on AIDS-related matters. Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases (NIAID), serves as the Associate Director for AIDS Research.

The first meeting of the AIDS Program Advisory Committee was held in February and provided an overview of the NIH AIDS research effort. This Committee was established to advise the Secretary and Assistant Secretary of Health, the Director of the NIH, the Associate Director for NIH AIDS Research, and the NIH AIDS Executive Committee on long- and short-term planning to meet AIDS research needs. The Committee will review the overall NIH AIDS research effort to make certain that it is consistent with internal efforts and complementary to efforts in external research settings. The Committee will also provide guidance on policy and other matters concerning the AIDS research effort. The next meeting of the AIDS Program Advisory Committee, scheduled for July 12, will address "HIV Vaccine Development and Testing." Potential topics for future meetings include: development and testing of antiretroviral therapeutics, basic research related to AIDS, animal model development, a review of efforts in the epidemiology and natural history areas, research on opportunistic diseases, and the AIDS research infrastructure.

Against a rapidly changing background, such as the report issued by the Institute of Medicine of the National Academy of Sciences (NAS) and the recent international AIDS conference in Stockholm, the NIH has made significant procedural changes to improve implementation of the Accelerated Solicitation and Awards Process (ASAP) for AIDS research grants, cooperative agreements, and contracts. Additional senior staff from the NIH and the Alcohol, Drug Abuse, and Mental Health Adminstration were temporarily assigned to the Division of Research Grants (DRG) to enable prompt assignment of incoming applications to appropriate peer review groups. Permanent measures, including assignment of additional resources and modifications to review and award procedures, are pending. For example, the DRG is in the process of developing a large, multidisciplinary AIDS Study Section that would be capable of reviewing all facets of basic and applied AIDS research.

As a result of the current moratorium on transplantation of human fetal tissue from induced abortions, an ad hoc panel of consultants to this Committee has been established. Judge Arlen Adams, recently retired from the Third Circuit Court of Appeals in Philadelphia, has been selected to chair this 20- to 25-member panel of consultants, consisting of a combination of ethicists, lawyers, religious leaders, scientists, physicians, and lay persons. A meeting of the ad hoc consultants is planned for mid-September. The report from the panel will be discussed by this Committee at an early November meeting.

History and Results of the Regional Meetings of the Advisory Committee to the Director, NIH

James B. Wyngaarden, M.D.
Director
National Institutes of Health

As a result of this Committee's deliberations during the meeting of June 15-16, 1987, a series of public regional meetings were held between November 1987 and March 1988 to further examine the Federal system of sponsored research and its impact on the biomedical research institutions in terms of quality, creativity, and scientific value. An expression of gratitude was extended to the host biomedical research institutions: the University of California at Los Angeles, the University of California at San Francisco, New York University, Forsythe Dental Center in Boston, the University of Texas Southwestern Medical Center at Dallas, Emory University School of Medicine in Atlanta, and Northwestern University in Chicago.

The purpose of the regional meetings was twofold: (1) to provide current information on NIH activities and the political context in which the NIH operates (i.e., the Federal budget process) and (2) to solicit the views of representatives of the scientific community (e.g., biomedical researchers, university faculty and administrators, and representatives of professional societies) concerning the impact of the Federal system of sponsored research on the health of biomedical research institutions. However, the major emphasis was on the second objective.

During the course of the regional meetings, public testimony was received from a total of 207 individuals, ranging from 13 to 42 per meeting. These individuals included postdoctoral fellows, principal investigators, department chairmen, dental and medical school deans, and representatives from private industry and voluntary health organizations. The regional meetings provided a wealth of information and recommendations that the Committee will consider at this meeting.

A preliminary analysis of the testimony from the regional meetings identified eight major areas of concern:

- peer review
- flexibility and continuity of research funding
- training and career development
- research facilities
- indirect costs
- research resources
- minorities in biomedical research
- animal research issues

An NIH working group was established for each of these areas to review the relevant testimony and provide a summary analysis of the views and concerns expressed in that testimony. The working groups have identified salient features, added background information for context, and suggested policy options, where possible, for consideration. The reports of these working groups were sent to Committee members as briefing materials and form the framework for this meeting.

The testimony also included a wide range of special interest topics: the importance of the Small Business Innovation Research (SBIR) Program; the need to increase emphasis in specific disciplines and diseases, such as nutrition, nursing research, and diabetes; and the need for increased investment in medical library systems.

Report of the Working Group on Peer Review

Claude Lenfant, M.D.
Director, National Heart, Lung, and Blood Institute
National Institutes of Health

Peer review is a topic of great interest both internally at the NIH and externally in the research community. A majority of the comments at the regional meetings concerned peer review,
with particular emphasis on innovative research and the track record of the investigator.

The most recent large-scale review of the process at the NIH was by the NIH Peer Review Committee, initiated by Dr. Wyngaarden in June 1987, as well as a number of special sub-committees that were simultaneously examining some aspects of peer review. The presentation consisted of topics raised by the NIH Peer Review Committee as well as the testimony from the regional meetings. Four areas for discussion were identified: philosophy of review, administration of review, reviewers, and the review process.

Philosophy of Review

The two major issues presented were the investigator's research record and the review of innovative research. Underlying these issues is the perceived decrease in award rates, which has increased pressure on reviewers to favor "safe" research and to give more emphasis to return applications. Innovative research, a subjective term, has not been sufficiently defined.

The NIH has taken some action to relieve the pressure on the system. Special grant programs have been created, e.g., the FIRST and MERIT awards, with provisions for more flexible use of funds and a 5-year award period. Institute-specific awards, e.g., the Outstanding Investigator Award for the National Cancer Institute (NCI) and the Javits Award for the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), have been created. At the National Heart, Lung, and Blood Institute (NHLBI), the Program of Excellence in Molecular Biology will provide 7-year awards. A significant change NIH-wide is that study sections are extending the duration of regular research grants. The mean duration of research grants in 1979 was 3.2 years, while in 1987 that figure had increased to 3.8 years.

Assessment of the effectiveness of assigned weights to review criteria is underway at the NIH. The suggested criteria weights were as follows:

Concept	30%
Protocol	25%
Investigator	40%
Resources	5%

Options cited for further action include the creation of special study sections for review of innovative research and increasing use of small grants and biomedical research support grants.

Administration of Review

The issue raised most by the Peer Review Committee was the workload of reviewers, while the workload of the investigators was raised mostly at the regional meetings. Data showed that the number of competing research projects had increased during the last 10 years to more than 18,000 this year. At the same time, the number of amended applications has increased to more than 4,000 in 1987.

Thus far, NIH has placed a limitation on the description of some sections of applications, reducing the number of pages. The Florida Demonstration Project will be expanded to all institutions. The review process for amended applications has become more strict and simplified. The communications system between the NIH and the research institutions is being improved, and the study sections are extending the term of regular research grant awards. All of these actions have helped to reduce the burden on reviewers and investigators.

Further actions that are being considered include simply asking investigators to highlight the amended sections of applications that are resubmitted and limiting the number of amendments.

Reviewers

With regard to the reviewers, the issues raised were selection methods and qualifications. The number of individuals serving on chartered study sections has doubled since 1982. Contradictory complaints–too many inexperienced reviewers versus using the same group of reviewers creating an "old boy network"–were heard in the testimony. However, the number of reviewers with prior service has not exceeded 13 percent.

The NIH is currently examining the option of mail review as opposed to committee review and is encouraging scientists to participate in the review process, appealing to a "moral obligation to serve." In addition, applicants are now being asked to recommend study section assignment.

Other options being considered are providing administrative support for investigators serving on study sections, a shorter term for reviewers on study sections, and allowing applicants to suggest potential reviewers for their applications.

The Review Process

Recent trends identified in the review process itself were twofold: (1) the increased volume of applications to be reviewed requires greater efficiency in the process while striving to maintain quality standards (quantity versus quality dilemma); and (2) the "priority creep," reviews in general have become increasingly favorable. In 1975, 26.7 percent of competing renewals received priority scores between 100 and 125, while in 1985, this category reached 53 percent.

As noted previously, the NIH is evaluating expanded use of mail review to improve the efficiency of the review process. Also under consideration is increasing the number of readers for each application from the current primary and secondary number. Efforts are also underway to increase the spread of priority scores. Dr. Wyngaarden has urged each Institute to use the percentile system, and, in the DRG study sections, appropriate information is being provided prior to grading the application. A study was done to assess whether changing the voting increment from 0.1 to 0.5 would increase the range of scores, but this showed little impact. In contrast, providing appropriate instruction to reviewers prior to grading applications has had tremendous impact.

In conclusion, additional options for future action include expanding use of ad hoc reviewers, mail review, and electronic communications; developing a system to constantly monitor and evaluate the review process; and determining the optimum number of primary reviewers for multidisciplinary research (e.g., a research project on the molecular biology of heart function). Peer review is the backbone of the research funding system, and changes to that system must not be counter-productive.

Discussant

Bernadine Healy, M.D.
Director, Research Division
Cleveland Clinic Foundation

Peer review is central to the unique way research is sponsored in the United States. Most of the biomedical research is conducted extramurally rather than in Federal Government laboratories, giving rise to a debate over the investment approach versus the procurement approach to funding research. In an investment approach, scientific merit is paramount. Underlying peer review is a principle of fairness and careful distribution of dollars, a public trust managed by the NIH. Fairness also applies to the scientific community, since careers can be made or broken based on ability to obtain funding. The output of such a principle is the establishment of a "meritocracy."

However, the majority of the concerns raised at the regional meetings were of process rather than principle. A strong commitment to objectivity and fairness was obvious, but a need to inject more wisdom into the review process also was expressed. The efforts currently made by the NIH to educate the reviewers and the testing of ad hoc reviewers before assignment to peer review groups are very important. A great scientist cannot automatically be considered fair and wise. In addition, assigning readers to applications would introduce an element of oversight and improve the dialogue at the peer review sessions. The peer review process is a judicial process with a mechanism for formal appeal, as well as the option to resubmit an application.

A formalized, ongoing system of monitoring and evaluation of the peer review process is important to the external perception of what the NIH is doing. The scientific community, the public, and, at times, the Congress wage a "relentless assault" on peer review. The peer review process is endangered by special interests and pork barreling. Educating the public about the peer review process is one defense against this assault, since the NIH clearly needs public support. The regional meetings and today's open forum are steps toward improved public understanding of the process. Fraud in science is a result of human failure rather than a failure of peer review; the way to deal with the problem is stricter peer review, as opposed to no peer review.

Open Discussion

The question of the failure rate of the peer review system was raised. No data on the failure rate, defined as the number of applications submitted that were funded initially but denied renewal, were available for the NIH as a whole.

The group discussed assistance for the new investigator with no research track record. Options to be considered were giving more attention to the training of new investigators and expanding initial awards to 5 years in length, such as the FIRST Award.

A suggestion to increase use of electronic communications to improve efficiency of the review process was supported by the Committee. On the day of a grant's review, the investigator should be available by telephone to answer questions from the reviewers. Such a conference call could eliminate the need for some amendments and resubmissions.

While the data presented by Dr. Lenfant revealed an increase in the number of applications and an increase in the quality of those applications, the basic problem is a lack of funding. Efforts in training young scientists and their potential to advance science as a whole will not be fully realized with the existing discrepancy between available funding and useful work proposed. The Committee recommended that the NIH be funded at least to the level of supporting 50 percent of the approved grants received.

While expanded use of mail review was desirable to augment the review process, this should not become an independent review entity. The suggestion to test ad hoc reviewers was excellent. Young investigators are under tremendous pressure in their research careers; therefore, a 2-year term on a review committee should be considered for them as well as for senior scientists. Multidisciplinary review is a major issue confronting the NIH.

The Committee discussed the value of the senior scientist serving on study sections as an "elder statesperson." One option suggested was that scientists who had previously served on a study section could be assigned as readers on amended and resubmitted applications. Their experience and fresh point of view could serve to keep study sections from forming a fixed mindset.

Concern over the quality of scientists who do serve on study sections was expressed. Citing jury duty as a parallel, some form of coercion to increase participation in the peer review process, especially among those world-famous senior scientists who have never served on a study section, was urged by one Committee member. After further discussion, the panel agreed that the attitude the NIH must encourage is a "moral obligation" to serve, not a compulsory approach.

Weighing review criteria should be career-phase specific so as not to be unfair to young investigators or a senior investigator who has not been funded as a principal investigator in recent years. The creation of special study sections for innovative research was termed an unworkable and unwise alternative. Concern was expressed about a trend toward circumventing the peer review system, through congressional appropriations. As long as it is difficult to build laboratories or replace needed equipment through the system, other mechanisms will continue to be sought.

In response to a question from a Committee member regarding variation in funding levels among the Institutes and the possibility that this imbalance would discourage investigators in certain areas, the periodic nature of grant applications and the substantial out-year commitments generated by the number of continuing previous awards was explained. In the same year, one Institute may have a 22 percent award rate, while another Institute may be at 45 percent. Each Institute and Division has a separate budget, and the NIH has no authority to transfer funds from one to another in order to balance out these discrepancies.

While the current research emphasis, in which training is part of the research, may be cost-effective, this benefit must be weighed against the cost to the career development of the individual investigator. The scientific community owes a great debt of gratitude to minority scientists who have served on study sections and advisory committees of the NIH; minority scientists are devoting triple the amount of their time to such service as the majority scientists. Recognition should be given to those minority scientists who have served, often to the detriment of their own careers and the training of their students.

A member of the Committee suggested that specific instructions be placed on the grant application to reduce the level of detail to be provided. While applauding recent changes imposing limitations on the number of pages in certain sections, he commented that in reviewing grants for Swiss and German granting agencies the process was much simpler, but the quality of the work produced was as good as in the United States where the writing and reviewing processes take a great deal more time. Such simplification is being looked at very carefully by the NIH.

Competition is important to the development of science. The NIH funding system is not a lone funding source, but one which complements and interacts with the private sector research being done.

Report of the Working Group on Research Resources

Betty Pickett, Ph.D.
Director, Division of Research Resources
National Institutes of Health

The presentation covered three main topics: the Biomedical Research Support Grant (BRSG), clinical research resources, and access to human cells and tissues for research.

The BRSG provides institutions with flexible support to enhance, strengthen, and stabilize their biomedical and behavioral research programs. In 1988, a total of 618 awards were made in this program with an average award of about $92,000, down from $112,000 a couple of years ago. The BRSG is limited by law to 15 percent of the funds available for NIH research grants. While the program has never exceeded a 1969 high of 8.5 percent, currently funding is around 1 percent

of the NIH research grants base. The use of these funds is locally determined and is usually for purposes not covered in the usual research grant mechanisms, such as pilot studies, support for new investigators, and shared resources.

The needs identified in the public testimony included support for new investigators and physicians, pilot studies, and interim funding. Perceptions that funds were too limited to meet the growing research demands and that the program was unstable were two serious problems identified. Others expressed concern about the program's threshold—at least three Public Health Service (PHS) awards from the list of eligible awards totalling at least $200,000—and suggested lowering this requirement to allow small health professions schools that are just beginning to conduct research to apply for grants. Another suggestion was to allow a consortium of small schools to meet jointly the threshold for grants. The witnesses at the regional meetings and the working group recommended that the BRSG program be given long-term, sufficient, and certain funding.

The 78 General Clinical Research Centers (GCRCs) are the principal NIH resource for patient-oriented research. These Centers provide an environment for clinical research, hosting NIH-supported investigators as well as investigators from other agencies and the private sector. The GCRCs support both inpatient and outpatient research, provide core laboratories for key analyses, and most have a dedicated computerized data management system. Funding for this program has expanded from $3 million in 1960 to $103 million in 1988.

The public testimony on this area concerned the need to provide sufficient funding to assure viability of the clinical research facilities. Research career development for junior physicians should be given more support, and the perception that the Ph.D. is more successful at obtaining research funding than the M.D. was expressed.

Participation in four NIH special awards in the area of clinical research—the Clinical Investigator Award, the Clinical Associate Physician Program, the Physician Scientist Award, and the new Dentist Scientist Award—is increasing. These awards provide salaries and funds for supplies and equipment. Data were presented on RO1 applicants by degree, showing that M.D.'s who applied had success rates similar to Ph.D.'s though many fewer M.D.'s apply. Thus, while the size of the pool of applicants varies greatly, the individual investigator experiences are common.

While NIH support for the GCRCs has been nearly static, accrued third-party payments have decreased sharply. Patients in the GCRCs are paid for in three ways: Category A patients are in the center for research purposes only and are funded entirely by the grant; Category B patients are in the center for routine diagnosis and treatment, paid by third-party payers, and also participate in the protocol, paid by the grant; and Category C patients are "boarders" in beds rented from the center by area hospitals. The overall trend toward more outpatient days at the center has helped them get through tough budget times so far.

With regard to research career development opportunities for physicians, the NIH must determine what an optimum number of participants in these programs should be. Were the 1,200 supported in 1986 the right number, or were there additional priority applicants who were not funded?

The testimony at the regional meetings also stressed the need for human cell and tissue resources for highly promising research, specifically that of fetal tissue in diabetes and Parkinson's disease research, and urged accessibility. In 1987, the Congress directed the NIH to support the National Diseases Research Interchange, a clearinghouse for human organs, tissues, and cells related to all diseases for research purposes, and to evaluate the need for such a

resource. The National Biomaterials Resources Committee held public hearings and advised that human cells and tissues were essential for research and that the NIH should continue support to meet current and future research needs in this area. The NIH plans to support a human cell and tissue resource, through contract procurement, by the end of 1988.

Discussant

Robert Bock, Ph.D.
Dean, Graduate School
University of Wisconsin

The Congress, the public, and the researchers need to be educated about the value of the BRSG Program. Representatives in the audience from the American Association of Universities, the American Association of Medical Colleges, and the American Society of Microbiology were thanked for their assistance in this education effort.

As an add-on activity to the BRSG Program, by Presidential initiative that mandated that every Federal agency target a number of high school research apprentices, the NIH has developed the Minority High School Summer Apprentice Program, which is geared toward minority high school students with the goal of introducing them to the research experience. Each institution that is eligible for a BRSG is also eligible for support for minority high school science interns to spend a summer session at their institution.

The current climate of cost containment for health care has put additional strain on GCRCs. Costs are now monitored so carefully that an extra day or an extra test will be challenged. The GCRCs may serve as models for high-quality clinical research, but they cannot be expected to do it all. Clinical trials, foundation interest in specific diseases, and the roles of the categorical Institutes must be considered as part of the total picture in clinical research funding.

Open Discussion

In view of the 15 percent ceiling on BRSG funding, the Committee questioned whether a legislatively mandated minimum of 5 percent of the NIH grants base would be useful. Such a mandate would result in a fourfold increase over the current level, but this would be useful only if additional funds rather than transferred dollars were provided.

The Committee recommended that funding for BRSG be increased and that the NIH encourage the institutions to use these grants for innovative research rather than establishing a special study section for innovative research.

A Committee member asked whether data were available on the success of investigators who receive a BRSG of $7,000 to $10,000 in later obtaining an NIH or National Science Foundation (NSF) research grant. Anecdotal information was available through tracking investigators who received pilot study funds. The new FIRST Award, as well as training grant awards such as CIBA, may be the place to begin systematic studies.

Report of the Working Group on Research Facilities

Jay Moskowitz, Ph.D.
Associate Director for Science Policy and Legislation
National Institutes of Health

Historically, biomedical research facilities construction has been funded by a combination of Federal and State appropriations, gifts from foundations, and donations from private individuals and corporations. A 1986 NSF survey reported that the Federal Government is responsible for about 10 percent of current facilities construction funding. This percentage is expected to decrease rather than increase. Federal funds support 35 percent of facilities construction at private institutions versus less than 1 percent at public institutions, where construction is funded mainly by State governments.

Ample precedent for a Federal leadership role in research facility construction exists, dating back to the Health Research Facilities Act in 1956. However, no funds were provided for construction after Fiscal Year (FY) 1968, and the NIH-wide construction authority was terminated in 1974. Since then, the NIH has received construction authority for specific purposes. Most recently, Congress appropriated nearly $24 million in FY 1988 to AIDS research for repair, modernization, and expansion of existing facilities and purchase of equipment. While specific construction authorities for the NCI, the National Eye Institute (NEI), and the NHLBI remain in effect, no funds were allocated for construction in the last fiscal year.

A lack of consistent support for new facilities construction and renovation and repairs to existing facilities may cause the Nation to lose ground in maintaining its excellence in biomedical research capability. Trends affecting the need for facilities include the unprecedented growth in scientific knowledge (e.g., molecular and cellular biology, genetics, and immunology), rapid development of technology such as magnetic resonance imaging, and increased need to comply with chemohazard and biohazard regulations.

The testimony at the regional meetings concerned two major components: the magnitude of unmet need for research facilities and the roles and responsibilities of various sectors in addressing that need. Recent studies to assess various aspects of the facilities issue were reviewed. The 1985 Survey of Cancer Research Facilities Needs estimated that $2 billion of new facilities would need to be built by 1990, while one fourth of the existing cancer research space was in need of substantial renovation. According to a congressionally mandated NSF study in 1986, entitled "Science and Engineering Research Facilities at Doctorate Granting Institutions," the changing nature of research, requiring more sophisticated environments, caused the need for facility construction more so than the age of facilities. Also in 1986, the Office of Science and Technology Policy (OSTP) published a study entitled "Report of the White House Science Council Panel on the Health of U.S. Colleges and Universities." The panel stated that Federal funding would be required if universities are to bring research facilities and equipment up to an acceptable level. The panel recommended $10 billion over the next 10 years, with $5 billion from Federal and $5 billion from non-Federal matching sources. The reports by the Government-University-Industry Roundtable of the NAS and the 1987 Joint Task Force on Medical Library Assessment were also cited. The second NSF Biennial Survey of Research Facilities is now being conducted in collaboration with the NIH, and results will be available in September 1988.

Direct quotations from the testimony at the regional meetings were used to illustrate the broad range of need expressed in the biomedical research community. The testimony highlighted the following specifics: "Most dental schools have inadequate and/or outdated research facilities . . . Most of the biophysical and biobehavioral laboratories being used by nurse scientists are 10 to 15 years old . . . Although the recent BRSG Program for small equipment was helpful, it represented a very small drop in a very large bucket. We need replacements for large laboratory equipment . . ."

A common belief is that the scope of the research facilities construction problem is too great for the Federal, State, or private sector to remedy alone; therefore, a partnership of some kind is necessary. According to the 1986 report by the Government-University-Industry Roundtable, no combination of universities and industries would have substantial impact on the problem with only token Federal support.

According to the testimony at the regional meetings, there is a need for a strong and well-defined leadership role for the Federal Government. Consideration should be given to an overall NIH construction authority, while individual institute-specific authorities should be maintained. Recently Senator Kennedy introduced legislation (S.2222) to address this research facilities issue.

Discussant

David Korn, M.D.
Vice President and Dean
School of Medicine, Stanford University

The working group's recommendations in the area of roles and authorities were summarized. First, the Federal Government should play a leadership role in addressing the Nation's biomedical research facilities needs. Second, the NIH should be given overall construction authority, but this authority should not supersede existing Institute authorities nor preclude establishment of additional new authorities for other Institutes. Engineers, architects, and other professional staff, as well as necessary operating funds for the Institutes of the NIH, should be provided to support this mission. Third, the selection process should be based on scientific merit with a two-tier peer review process. Some level of flexibility in funding should be maintained to support emerging institutions of excellence. The group strongly favored merit evaluation as adjudged by peer review over the recent prevalence of congressional earmarking of funds. The current Senate authorization bill states, "The pork barrel process is at best an inefficient and haphazard method to address such a critical need."

The working group also had several recommendations for financing biomedical research facility construction. First, new monies are needed; an approach that would diminish existing biomedical research and training support is undesirable. Second, there should be an equity approach to financing, with a 50-50 matching requirement for Federal funds. Even with matching grants,
debt financing will be necessary in view of the huge need for renovation and facilities construction. To finance this approach, the group recommended that the indirect cost use allowance be raised from 2 percent to 5 percent and the equipment allowance raised from 6-2/3 percent to 20 percent. This amounts to a more realistic assessment of the useful life of facilities. For example, buildings should be considered to have a useful life of 20 years rather than 50 years and equipment 5 years rather than 15 years.

The working group also suggested separate indirect cost allocations for capital and operating expenses to prevent an erosion of funds that the NIH currently uses for direct support of research. However, indirect costs are currently underfunded, so new monies would be required. Findings from a study conducted at Stanford on indirect costs were relevant to the facilities construction issue. The report stated that due to the reduction in Federal funds for facilities construction over the last 25 years, the cost of supporting facilities has shifted from direct to indirect. The burden of building and maintaining these facilities falls on the universities, and the costs incurred are charged back to the Government in the form of depreciation. This change in the way the Government is paying for facilities, from direct to indirect, has led to increased indirect cost rates for research. At private universities, this has resulted in a tremendous increase in indirect costs, as opposed to public universities that use State funds for facilities.

The working group recommended that the Government expand the construction loan guarantee program, limited to undergraduate academic or housing facilities, to include biomedical research facilities. Also, the recently enacted Tax Reform Act should be revised to encourage philanthropy, stimulate tax incentives for facilities construction, and eliminate the cap on issuance of tax-exempt bonds.

Specifically, the group proposed an NIH Facilities Construction Program, a 10-year program with a 2-year pilot. Funding levels suggested were $100 million for the first year, $200 million for the second year, and $350 to $500 million a year for the remaining years. Individual awards should be limited to a minimum of $250,000, but not more than 5 percent of total appropriation in a year to any one institution.

Open Discussion

In response to a question on the allocation and management of the proposed construction program, Dr. Wyngaarden proposed that the construction program be managed by the Division of Research Resources (DRR), as were the programs of the 1950's and 1960's.

There was considerable interest in the report of the facilities committee at both the House and Senate hearings. The Department of Health and Human Services pointed out that the report examined the facilities issue in isolation and had not weighed the need in competition with other Federal spending priorities.

Universities are having difficulty obtaining funds for biomedical research construction in some States, because funds are earmarked for economic development of the State with for-profit industry standards. A matching requirement like that proposed for the construction program would help to ease the flow of State funds. The scientific community has been fortunate that private philanthropic foundations have outstripped Federal and State funding of construction of research facilities in the 1980's.

The view that facilities were in a "crisis situation" was strongly challenged. The Committee was urged to keep in mind that the resources available for biomedical research are finite, and that major support of new facilities is likely to erode support of ongoing research. One Advisory Committee member noted that the British, while maintaining a vigorous scientific enterprise and pharmaceutical industry, have elevated facilities deterioration "to an art form." Another Committee member cautioned that the desire to maintain an individual Institute's construction authority seemed to be "scientific pork barreling."

Report of the Working Group on Animal Research Issues

Robert Whitney, D.V.M.
Director, Division of Research Services
National Institutes of Health

Two major issues in the animal research area were identified from the testimony at the regional meetings. First, there was concern about recent and proposed regulations and the increase in costs that may evolve from those regulations. Second, there was a request for the NIH to lead a proactive campaign on the benefits of animal research to counter the increasing animal rights activism. Generally, the witnesses felt there was an inter-relationship between activism and increased regulation.

In the 1960's, a degree of self-policing in the area of animal research was evident prior to any Federal regulation in the *NIH Guide to the Care and Use of Laboratory Animals* and the Association for Accreditation for Laboratory Animal Care. Both the Guide and the Association existed before the 1966 Animal Welfare Act.

The 1980's has been a tumultuous decade thus far for animal rights activists, beginning in 1981 with the Silver Spring Monkeys and the emergence of People for the Ethical Treatment of Animals (PETA). The issues raised by the initial seizure of monkeys by the Montgomery County Police Department in Silver Spring, MD, based on allegations of cruelty, were raised again just weeks ago in congressional oversight hearings for the NIH.

Since 1984, there have been almost monthly break-ins, thefts, and vandalism across the country by the Animal Liberation Front (ALF). In California alone, there has been over $10 million in damage. Two films being used by the animal rights activists are entitled "Unnecessary Fuss" and "Breaking Barriers." While the first film showed actions that were definite violations of the Animal Welfare Act and PHS policy, the second did not.

An American Medical Association national poll, conducted in February 1988, showed that nearly 80 percent of the American public approved of the use of animals in health-related research. That is a very significant number for the NIH to know.

In 1985, a number of Federal initiatives in the area of animal welfare were outlined:

- The Office of Science and Technology Policy published *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*, which served as the foundation for the sixth revision of the *NIH Guide for Care and Use of Laboratory Animals*.

- The NIH continued random site visits begun in 1984. Information obtained in these site visits led to revision of the PHS policy on humane care and use of laboratory animals in 1985, requiring mandatory institutional review of PHS applications and proposals for the first time.

- The amendment of the USDA Animal Welfare Act in 1985 was, and continues to be, the cause for the most concern to the research community. In response to proposed regulations in Parts I and II, the USDA received over 8,000 comments. Part III, which has not been published yet, will probably be the most controversial of the amendments. Two particularly troublesome provisions were noted: the simple phrases "provide for adequate exercise for dogs" and "provide for the psychological well-being of primates." No consensus exists on either of these areas, due to divergence of opinion regarding adequate in the first case and diversification of primates in the second case.

Recent NIH initiatives include a series of regional workshops and continued site visits. In response to legislation, specific RFAs are now being developed and issued for nonvertebrate model development projects. The DRR has increased the level of training for veterinarians in laboratory animal medicine. The NIH has increased its liaison with Congress in this area and has taken the lead role on several bills that would have a negative impact on the use of dogs and cats in research.

The NIH has been involved in outreach and education efforts in the animal research field. A coalition of organizations interested in the appropriate use of animals for research that includes over 60 voluntary national health associations (representing millions of signatories of a statement supporting continuing animal research) will jointly sponsor an educational event at the NIH later this year. In February 1988, the DRR organized a briefing for members of Congress and key staff members on the use of chimpanzees in AIDS research. Working with academia and industry, the NIH is continuing this series of congressional briefings, a good example that scientist involvement is a very important aspect. Scientists on the animal care committees have also been involved in development of investigator training that includes sensitizing scientists to public concerns.

A small number of researchers are actually using animals. A large number of the break-ins at labs were "inside jobs," emphasizing the importance of educating staff of what animals are used for and how they are protected. The scientific community must respond to this challenge by the animal rights activists in order to ensure the continuation of biomedical research to advance both human and animal health; however, the public must also be guaranteed of appropriate care and use of animals.

Discussant

Arthur Guyton, M.D.
Professor and Chairman, Department of Physiology and Biophysics
University of Mississippi Medical Center

Animal welfare organizations have a total of $30 to $50 million a year, a very large part of which is used to fight animal research. While the congressional briefings were useful, the scientists sometimes do not know all the facts. Therefore, a "fact book" for scientists should be produced. The NIH's leadership in this area has been quiet, and, perhaps, the NIH should reassess how much of a public stand it should take on the issue.

The Institutional Review Committees were cited as an example of burdensome regulations. In testimony from the regional meetings, it was stated that for every application that came before them the cost was approximately $500. While this was a substantial cost, the major costs were in the investigators' time and delay of the research. There is an important difference between "safe" research, in which an investigator can design a protocol a year in advance and adhere to it, and "real" research, which is innovative and frequently varies from the protocol.

In order to avoid breaking the spirit of the investigators, alternative types of review processes should be explored. A generic review in advance of the research could include information about the laboratory's general goals, the types of research to be done, and a review of its track record in past research efforts. Then a review in retrospect could examine specifics.

Veterinarians who were running the animal facilities are in a very difficult position, caught between the regulators and the investigators. The requirement for five different types of space to do surgery on animals larger than and including rabbits is overzealous. Human surgery has only three different areas: the preparation area, the operating room, and the recovery area. Aside from the cost of providing such a special surgical area, approximately $250,000, this creates unnecessary scheduling difficulties and logistical problems for the investigator. A clean laboratory should be sufficient for surgery as well.

Discussant

James Glosser, D.V.M.
Administrator, Animal and Plant Health Inspection Service
U.S. Department of Agriculture

As administrator of the Animal Welfare Act, the Animal and Plant Health Inspection Service has been very involved in writing the forthcoming regulations implementing the 1985 revisions to the Act. Congressional hearings giving clear legislative intent would have been helpful in this case, since "very scant language at best" exists on some of the issues. By fall 1988, the U.S. Department of Agriculture (USDA) plans to publish in the *Federal Register* both the final rules from Parts I and II, as well as the proposed regulations from Part III.

Four key points were identified: (1) the requirement for adequate exercise for dogs and establishment of a written program and system for fulfilling this requirement; (2) the requirement for a physical environment to promote the psychological well-being of primates and the development of a program and system to carry this out; (3) the requirement to minimize animals' pain and distress in experimental procedures; and (4) the requirement mandating Institutional Animal Care Committees in every animal research facility, along with requirements concerning membership and operation of this Committee. There is a great difficulty in defining terms such as "adequate" exercise and "painful" procedure.

Preliminary economic assessments have shown that the new regulations must be considered a "major rule" by definition, exceeding $100 million in costs. As such, the regulations fall into a special category. Increased costs include renovation, purchase of equipment, new construction, and additional staff (e.g., for exercising animals).

The USDA hopes to continue to cooperate with the NIH and other agencies to ensure the progress of biomedical research and the ethical treatment of animals by a civilized society.

Open Discussion

The regulations being drafted do not apply to the Humane Societies unless the animals are sold there.

One Committee member said that it was ironic that in the State of Maryland most of the legislation regarding treatment of animals has been introduced by the representatives from the county where the NIH is located, Montgomery County. He added that he was appalled by the lack of knowledge of scientists who have appeared before the Maryland General Assembly on

issues of nonanimal models available and random-access animals. A massive educational effort among the scientists on the facts is needed if they are, in turn, to help to educate the public on the animal research issue. "We have met the enemy, and he is us, much more so than PETA or the other animal activists." He recommended that the NIH consider producing a fact book as Dr. Guyton had suggested in his comments.

The perception that the NIH was not doing enough on the animal research issue was troubling. "Clearly, we're not reaching the public in the way that we have to reach them." The NIH animal initiative program, planned for the near future, has a three-pronged approach: (1) educating the Congress through briefings; (2) involving the patient coalition in supporting animal research; and (3) developing a curriculum for junior high and high school students that includes an explanation of the need for and uses of animals in research.

Attention should be focused on the compassion of the scientist who elects to go into biology because of a reverence for life and concern for the suffering of any life form. Agreement on the appropriate care of animals used in research does not have to be linked to what the investigator will study. Modeling cannot replace animal research. The public needs to understand that the basic principles on which modeling is done need to be verified in the research laboratory.

A public television program by "NOVA" in cooperation with the NIH and the NSF on animal research or a segment on "Nightline" with Ted Koppel were recommended. Another avenue that the NIH could explore for public education efforts would be to contact private fundraising organizations, such as the Juvenile Diabetes Association, to enlist their aid. "West 57th Street" did a balanced and fair presentation recently on the use of chimpanzees in research. However, in working with the media on a public broadcast, the NIH has no control over the agenda to assure a fair and accurate presentation.

The scientific community is still on the defensive, trying to persuade the public that "we really don't hurt the animals that much." Instead, a more positive approach should be taken, focusing on how many lives have been saved and how many people have been spared suffering because of animal research gains. The issue needs to be presented as a tradeoff.

A citizens group called Incurably Ill for Animal Research (IIFAR), which began in the Southwest, is now spreading to other areas of the country. Members of IIFAR are willing to appear at public hearings to rebut the animal activists.

Report of the Working Group on Flexibility and Continuity of Research Funding

Claude Lenfant, M.D.
Director, National Heart, Lung, and Blood Institute
National Institutes of Health

The first area examined by the group was interim funding, defined as partial support to prevent a hiatus of funding pending final determination of a competing renewal application. The benefit of interim funding is that it allows maintenance of the research team pending the final decision on a competing renewal grant application. However, the cost of providing funding for all competing renewals would be extremely expensive. The NIH provides interim funding on a case-by-case basis, using specific criteria, and usually at minimum maintenance levels. The group recommended that the NIH expedite the review process for amended applications to reduce the need for interim funding in the future. Investigators should also be encouraged to submit their applications early, rather than at the last minute.

The group considered whether carryover support, transfer of an unobligated balance at the end of one budget period to a subsequent budget period, and no-cost extensions should be expanded to increase funding stability. The unobligated budget for the NIH, currently around $80 million, is used for carryovers and no-cost extensions, as well as for funding new research grants and competing research grants.

Full funding and cutbacks were also discussed by the group. Decreasing award rates and improving priority scores have resulted in a large number of unfunded applications of high scientific merit. The NIH has chosen to apply an overall reduction in funding to all of the grants, which has increased to an average of 13 percent for competing grants and 10 percent for noncompeting grants in FY 1988.

A lack of long-term funding adversely affects the ability of institutions to conduct long-term scholarly pursuits and to attract the best young scientists. The NIH has extended the average duration of regular research grants from 3.2 years to 3.8 years. In total grant years, this increase accounts for 14,000 of the total of 78,000 grant years in 1987, a substantial increase. Another option suggested for further NIH action was to study the potential role of the BRSG in stabilization.

Discussant

Bernadine Healy, M.D.
Director, Research Division
Cleveland Clinic Foundation

When the issue of stability of funding is discussed, the type of funding must be defined. If the NIH is viewed in the aggregate, the funding has been stable, and a steady moderate growth in the NIH budget has occurred over the years. The perception of instability of NIH funding expressed at the regional meetings was that of the individual investigator in the individual laboratory. This microview must be distinguished from the aggregate picture.

Science is, by its nature, a high-risk venture. Thus, a certain amount of instability is inherent in the profession. Whatever security is afforded to the individual investigator should be the responsibility of the university or research institution, not the Federal Government, she continued. Use of BRSG funds to assist investigators with interim funding is one example of how the university can provide stability.

The role of the Federal Government to help provide stability can be improved by extending the duration of grants, expediting the review process, and allowing carryover support and no-cost extensions. However, determination for carryover support and no-cost extensions should be made by the university. The investigator must have the flexibility to change the protocol and redirect efforts. Flexibility is vital, but it is not related to stability.

Open Discussion

The NIH should be complimented on their funding stability relative to other funding agencies. However, the present BRSG funding level is not close to taking care of the needs of research institutions.

The importance of the no-cost extension as a moneysaving device for the NIH, as well as a method for extending the opportunity for better science, was stressed.

While some degree of insecurity is inherent in science, the problem among today's young people is a deeper one. More than just uncertainty about whether they can succeed, young scientists have a perception that there is such a limited opportunity for funding even if they are really excellent, that they choose the more financially secure route of clinical practice over the academic career. The group should focus on those individuals in whom they have already invested a considerable amount of training dollars.

A commitment to research does not mean an individual is enthusiastic about a commitment to uncertainty. As an investigator gains experience in the research system, he or she learns some of the strategy necessary to ensure constant funding, but a new investigator cannot be expected to have that degree of sophistication. Therefore, the new investigator must bear a great deal of uncertainty. Concern was expressed about returning more discretion to the local university in the use of funds, because local judgment has its political overtones. A great virtue of the peer review system is that an investigator at any level on the academic ladder has the opportunity to obtain support based on merit.

Responding to comments on systematic cutbacks in research grants, Dr. Wyngaarden noted that the NIH would prefer to pay full cost on whatever number of grants it could support each year. The number of new awards to be made each year is specified in some years by the Congress, in some years by the Office of Management and Budget (OMB), but never by the NIH. The study sections reduce the size of the grant request by an average of 15 percent, with an additional cutback of 13 percent for new awards and 10 percent for renewals imposed across the board. However, investigators usually request an increase of 30 percent from one grant to a competing renewal, so the average research grant does increase between 8 and 10 percent over the previous year.

A plea was made for some form of Institute-wide consideration to stabilize the Clinical Investigator and Physician Scientist Awards, key transitional awards that experience serious fluctuation in grant cycles within categories.

The risks associated with a research career are the tradeoff for living a "fantastic intellectual life." Two models that had surfaced in the discussion thus far: the "Federal judgeship" model, in which, once the funding is obtained, it continues forever, and the "competitive approach," in which only the best should succeed. In contrast to a small country such as Sweden where there are only a handful of medical schools, the United States has 120 medical schools and several private research institutes. By virtue of the broad number of opportunities in this country an intense feeling of competition can be lost in the process.

More funds should be focused on the new investigator award, the K awards, which help young scientists get into the system. After they are in the research system, they should be able to compete for the regular research grants. The FIRST Awards and the Physician Scientist Award are NIH efforts to address that concern.

Report of the Working Group on Indirect Costs

Edward McManus
Deputy Director, National Eye Institute
National Institutes of Health

Indirect costs associated with research grants sponsored by the NIH include categories of depreciation and use, operation and maintenance (e.g., heat and lights), and general administration. For example, the office of the president at some universities is funded out of the indirect cost category.

The regional meetings encompassed many comments about indirect costs, both positive and negative, representing the split between investigators and administrators. Four major themes were identified from the regional meetings: (1) the impact of indirect costs on the competitive ness of the investigator's application; (2) the disparity of the indirect cost rates between institutions; (3) the need for education of faculty as well as NIH staff on the uses of indirect costs; and (4) the need for support of the infrastructure.

Between 1946 and 1956, the indirect cost rate was fixed at 8 percent. When the need for support of the infrastructure was expressed, the rate was raised to 15 percent in 1956. However, training has remained at 8 percent through the present. In 1963, the indirect cost rate, still fixed, was raised to 20 percent of direct costs. From 1966 to the present, the concept of "actual indirect costs" came into vogue at an average of 45 percent of direct costs. This rate of actual indirect costs can range from 30 percent to 80 percent at some private institutions.

Currently, in actual dollars, indirect costs amount to $1.4 billion, on which there is very little NIH oversight. Most of the oversight on that money comes from accountants at HHS. The indirect cost has remained at an average of 31 percent of the total costs since 1984.

The indirect costs are now listed on the grant applications. While study section members are told that they should not use this information in their final determinations, some investigators are concerned the figure will have an impact on competition for grants. On the other hand, the presence of this number has highlighted the fact that indirect costs must come out of the NIH budget.

If the indirect rate goes up to support the infrastructure, for example, then there are fewer funds available for direct costs of research. This is the dilemma faced by the scientific community.

The working group's conclusions on indirect costs included a recommendation for an annual review of indirect costs by the NIH to provide a formal focus on policy changes by OMB and other auditing agencies. The financial impact of policy implementation must be realized and discussed in the scientific community. An education program on indirect costs may be the most significant action the NIH could take in this area. The group recommended that a model course be developed by the NIH for scientists, university faculty and administrators, the grant reviewers, and the NIH staff. In addition, future studies and demonstration projects, such as the Florida

Demonstration Project, should be supported. Specific goals include a definition of "equivalent rate," so that different institutions could be compared, and the development of standardized components and a short form for indirect costs.

Discussant

Cornelius Pings, Ph.D.
Provost and Senior Vice President for Academic Affairs
University of Southern California

The findings of the Ad Hoc Committee on Indirect Costs, appointed by the Executive Committee of the Association of American Universities (AAU), will be published after the final meeting in July 1988. Most of the Committee members, now university representatives, had former experience as principal investigators. The AAU Committee heard from a number of witnesses, including representatives from OMB and the regulatory agencies, and held regional meetings in Los Angeles, Chicago, and Boston.

The relationship between the Federal Government and the research institutions appears to be shifting from an informal partnership to a more formal relationship in which the Government views the universities as contractors providing services. This more formal relationship will put additional strain on the indirect cost recovery issue. Full cost reimbursement has been a myth since 1948. Certain categories of cost are disallowed, and within the allowable categories the agency usually bargains down to a final rate agreed upon with a "take it or leave it" result. Indirect cost rates are likely to increase in the near future as a result of facility-related and equipment-related matters.

One conclusion the AAU Committee reached was that the current system (OMB Circular A-21) should not be scrapped completely, but rather amended, according to the consensus expressed at the regional meetings. Certain components of the indirect cost rate, usually departmental administration, were termed "soft" by the Government agencies, while other costs, such as facilities and equipment, were almost universally acknowledged as necessary and proper. Indirect cost rates do vary considerably among universities and even among departments. The Committee reaffirmed that no one was overrecovering, and the Government auditing process requires costs to be accounted for in detail. Reasons for the variations in rates include use of facilities for different types of research, differences in regional costs, the negotiation process that occurs with Federal agencies, and underrecovery by a number of institutions. At times, the underrecovery was a deliberate tactic of the university to keep the total costs of research down and give the investigator a favorable position to compete for grants. Administrators and investigators believe that the indirect cost rate affects competition, although no evidence has been found to support that view. The principal investigators' major complaint was that facilities were not being maintained despite overhead rates claimed for that purpose.

The AAU Committee made several recommendations. The Committee decided that education efforts on indirect costs would be fruitless among faculty members. More direct charging and consistency in the base were recommended. In addition, the rate should be split into two separate categories, a facility and equipment rate and a second rate to encompass everything else, i.e., administration, library, and student services. With regard to the second category, the Committee suggested a standard set of threshold rates be established that an institution could adopt or could choose to document costs to recover higher amounts. This system can be compared to the income tax standard deduction on the 1040 form or the form A option for itemized deductions. The Committee believed this change could remove 80 percent to 90 percent of the institutions from the negotiation process.

Open Discussion

The question was raised whether indirect costs had become a virtually constant fraction of research costs regardless of annual budget variations. While no data were available on this question, experience has shown that once the rate had been set at a certain level it acquired an intrinsic irreversibility.

A comparison between indirect cost rates at universities, private industry, and Federal laboratories, as well as a comparison of the NIH with other Federal agencies supporting high-cost research such as USDA and DOD, would be useful.

Two issues that Committee members cited as most difficult for the public and the Congress to accept in the area of indirect costs were the variance in rates from one institution to another and the practice of some universities of returning a percentage of the indirect costs to the investigator. Can excess money returned to an investigator be considered a real cost? Splitting indirect costs into two components would be useful in explaining real costs. Universities should be careful never to use the term "rebate" in discussing indirect costs.

Report of the Working Group on Minorities in Biomedical Research

Ruth Kirschstein, M.D.
Director, National Institute of General Medical Sciences
National Institutes of Health

The overall figures for minorities in biomedical research are "dismal." During the period from 1976 to 1986 the percentage of blacks earning a Ph.D. decreased from 4.2 percent to 3.6 percent, while the percentage among Hispanics increased slightly during the same period. In 1986, the breakdown of students who earned a Ph.D. in the life sciences was as follows: 64 blacks, 72 Hispanics, 23 American Indians, and 3,958 whites.

The NIH initiated two complementary programs in the early 1970's to address this disparity, the Minority Biomedical Research Support (MBRS) Program and the Minority Access to Research Careers (MARC) Program. The MBRS Program is primarily a research grants program. Most grants are awarded to 2- to 4-year colleges, universities, and health professions schools at which minorities comprise at least half of the enrollment. These include historically black institutions, and majority institutions that have shown a specific commitment to minority students. MBRS grant support is for faculty members' individual research projects. The MARC Program is a research training and fellowship activity for undergraduates, graduate students, and faculty members.

In 1985, the NIH, through congressional mandate, began the Research Centers at Minority Institutions (RCMI) Program. These awards are for institutional developments to enhance the infrastructure. In addition, each of the NIH Institutes has special minority activities for biomedical research and research training for minorities.

These NIH efforts were generally praised at the regional meetings. Suggested improvements include: "seed" funds, sustaining funds, and consideration of the needs of minority scientists outside of affirmative action programs. Testimony stressed that Federal agencies could help most with additional funding for minority scientists during the critical first few years of their careers.

The working group concluded that the MBRS, MARC, and RCMI Programs should be continued, refined, and enhanced. The group recommended several options for NIH consideration, for both immediate action and long-range planning. First, all Institutes at the NIH should participate in minority research supplement activity. Also, administrative supplements should be made available to research grants to provide minority students with summer research experiences. Second, short-term training programs could be expanded to allow minority faculty to conduct research at other institutions. Third, the NIH should encourage minority scientists to apply for the FIRST Award. Fourth, the NIH should encourage minority scientists to apply for the Academic Research Enhancement Award (AREA) in greater numbers.

For long-range planning, the NIH should conduct a series of regional hearings at or near historically black colleges and universities (HBCUs). Each Institute should be asked to develop a 5-or 10-year plan to expand the national pool of underrepresented minority scientists in biomedical research. Finally, the NIH staff must become more involved in counseling and assisting minority scientists in preparing grant applications.

Discussant

David Satcher, Ph.D.
President
Meharry Medical College

Dr. Satcher expressed appreciation to the NIH for conducting the regional meetings and commended the working group for the quality of its report on minorities in biomedical research.

The role of minorities should be viewed in the context of the NIH mission to promote the health of all people of the Nation. By the year 2000, one-third of those people will be minorities. While genuine efforts have been made by the NIH and the MBRS, MARC, and RCMI programs have had a positive impact, those efforts are inadequate and must be significantly enhanced.

Options outlined by Dr. Kirschstein should be encouraged with one amendment. A critical alternative was for faculty from minority institutions to conduct research at minority as well as majority institutions when participating in short-term training programs. The relationships that have developed between Fisk University and Meharry in recent years were cited to support this amendment. In addition, while the NIH employs a substantial percentage of minority researchers, the number of minority scientists who reach top-level positions should be assessed.

There is a need to define the problem, to put the problem into perspective, and to agree to clear and measurable goals. The health status of blacks and other minorities in this country continues to lag significantly behind that of whites. Blacks and Hispanics are disproportionately at risk for AIDS. At the same time, problems of access to health care have increased for minorities who are poor in this era of cost-containment.

Furthermore, the expansion of the NIH's efforts to improve representation of minorities in biomedical research has not kept pace with the growth of the NIH's budget. In 1985, 0.931 percent of the total NIH budget was targeted for minority programs. In 1988, that figure has fallen to 0.875 percent. Budgets for MBRS and MARC have barely kept pace with inflation over the last 3 years. While the dollars have been static, the programs have expanded in scope to include 2-year colleges, high schools, and majority institutions that serve a large black or Hispanic population. Thus, there is even more strain on the limited funds.

The retention and promotion of minority faculty are critical, challenging "us" to respond to the problem collectively. The Committee should: (1) set clear and measurable goals, such as setting aside 3 percent of the NIH budget for minority-targeted programs within 5 years; (2) strengthen programs that are in place and working (e.g., MBRS and MARC); and (3) encourage more cooperative efforts and cofunding (e.g., the Comprehensive Minority Biomedical Program at NCI).

Minorities should not be inappropriately lumped into one group. There are specific concerns for blacks, Asians, Hispanics, and Native Americans, which deserve attention. During the NIH centennial celebration in 1987, a national symposium was held at Meharry, co-sponsored by the NIH and the Association of Minority Health Professions Schools. This successful symposium reached nearly 200 minority students, but perhaps more important, it led to the establishment of an annual symposium on careers in biomedical sciences. Last year's symposium in Atlanta drew 800 students. This is one example of what can result from a cooperative effort.

Open Discussion

The need for long-term planning was echoed by the Committee. The fundamental problem, indebtedness of minority physicians at the time they complete their residency training, has not been effectively addressed to date. At a recent retreat of PHS agency heads, one of the action items for consideration was a loan repayment or loan forgiveness type of program. In addition, a paper is being prepared to address the amount of indebtedness of a medical student, which is an average of $28,000, with women and minorities having an even higher amount of debt. The difficulty of recruiting minority individuals at the Medical Staff Fellow level to do research at the NIH is also of concern.

Without the NIH special programs, the "dismal" figures Dr. Kirschstein presented would be even more disappointing. There are not enough minorities represented on this Committee, an indication that more needs to be done. The NIH has, through its connection to all of the MBRS institutions, the best network in place to make a difference in this area. The NIH should establish additional outreach and education efforts to high schools through their MBRS contacts. The system is already in place, and the return on the funds it would take would be "unbelievable." The success of Xavier University with the help of the MBRS and MARC Programs was cited as an example of a small investment yielding a large return. The school is small, with around 1,600 students, but it is number two in placing young minorities into medical and dental schools. "We don't mind taking risks, and we know what the returns can be," Dr. Norman Francis, President of Xavier University, said. "We're talking about investment, not handouts."

An educational initiative has been approved by Dr. Wyngaarden, and the subcommittee will address issues such as where to begin, for example, junior high school or high school, and should education about the sciences be presented as well as career opportunities. Preliminary discussions have noted that materials will be produced in Spanish as well as English.

The decline in minority applicants to medical schools has been significantly less than the decline in majority applicants. In addition, the Robert Wood Johnson Foundation report last year noted that the overall quality of the applicant pool for minorities has increased, while for majorities it has declined.

The panel discussed what is being done to support and strengthen the faculty of minority schools in mathematics and natural sciences. The NSF Program was cited as one model. The program is very small, and last year funded two minority research centers of excellence, one at Meharry and one at the Howard School of Engineering. The essence of that program is to strengthen the research base of the institution and to develop linkages to junior high schools, high schools, and undergraduate colleges. As a result of this program, Meharry has high school and college students on campus this summer, as well as undergraduate college faculty. However, another major area of concern must be the decline in the percentage of minority high school science teachers in the public schools from the current 8.5 percent to an estimated 5 percent by 1990.

Underlying all of the efforts underway or proposed to increase minority participation in biomedical research is a lack of a Federal program to focus explicitly on the issue of competency of faculty in math and science. This void will also need to be addressed in the near future.

The very heavy teaching load experienced by faculty in predominantly minority institutions results in difficulty in maintaining their own research skills at the cutting edge of science. One solution would be an NIH program to enhance the sabbatical opportunities for those individuals with institutions that have major NIH research programs. This approach to providing specific

funds for release time for faculty and hiring of extra faculty were two of the options the working group proposed. This could be done by NIH as supplement to the regular research grants for minority faculty.

At the NIH Alumni Week last year the dean from Yale University commented that with NIH assistance his institution now has seven faculty members for each student admitted. On the other hand, Meharry has two students for each faculty member, which is an improvement from four students per faculty member in 1982. This statistic gives a new kind of respect for faculty at schools like Meharry, Xavier, Morehouse, and Drew, when they are able to join together on grant proposals and compete for funds.

Echoing Dr. Satcher's comment that minorities should not be lumped into one category, one Committee member cautioned that an "us" and "them" mentality can lead to a numbers game in affirmative action, resulting in meeting the quotas with little concern over how they are met. This type of system will not successfully meet the needs of the people it serves. The issue is not finding the numbers, but rather finding the people who need an opportunity to demonstrate their abilities and to grow.

Educational efforts should include the investigators at majority institutions as well, noting that having minority students in summer research programs provides a rewarding two-way exchange.

Approximately 30 percent of the NIH employees overall are minorities. Of that number, 28 percent are black and 52 percent are women. The minorities are concentrated in the nonscientific areas of the various job classifications. The NIH record of attracting minority scientists through the associate programs and of promoting them to permanent rank has been poor.

Many of the majority institutions have had affirmative action programs to attract minority students into medical schools since the early 1970's. Cohort studies of these students and the careers they now have would be informative in terms of psychological motivations and financial pressures that may have influenced their decisions.

The NIH has been disappointed by the type of data it has been able to collect through alumni offices. However, the NIH could fund such studies to be done by the universities, which seem to have obtained better data on their graduates for fundraising purposes. Several studies of this nature have been done in fragmented style, but no concerted efforts have been made to bring this information into a central clearinghouse.

The scientific community has damaged many fine minority investigators by "working them to death" as representatives on numerous committees and councils. As recognized representatives of their minority group, they feel compelled to serve in this capacity, often at a detriment to their own career development.

The NIH should make use of the Survey of Earned Doctorates, conducted by the National Research Council, in order to get a picture of the total population. This study is recommended because followup studies include enough minorities to have statistical significance.

Report of the Working Group on Training and Career Development

Katherine Bick, Ph.D.
Deputy Director for Extramural Research
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The issue of the support and future of research training was one of the most often expressed concerns at the regional meetings, second only to peer review concerns. At every meeting across the country, the statement that more support is needed for the NIH training programs was heard.

Since 1976, the NIH has supported about 10,000 to 11,000 trainees per year. While the amount of funding has increased over the years, the number of individuals trained has not changed significantly over the last decade. The NIH provides research training and manpower development through the National Research Service Award (NRSA) Program, the Research Career Program, and the Clinical Associate Program. In 1988, the NIH will support over 2,000 post-doctoral physician trainees for $30,000 each and will make nearly 600 fellowship awards to both physicians and dentists for $32,000 each.

The NRSA Program, through the Medical Scientist Training Program (MSTP), will provide support for 719 trainees to obtain the combined M.D.-Ph.D. degree. No corresponding program for dentists exists. The Short-Term Training Program for Health Professionals, also supported by the NRSA budget, accounts for nearly $2.5 million and provides 3-month exposures to research for students already committed to clinical careers in health professions schools.

The Research Career Program, funded from research grant budgets of the institutes, includes various specialty awards to fulfill specific needs from each institute, such as the Clinical Investigator Award, the Physician Scientist Award, and the Dental Scientist Award. This year, nearly 1,500 of these awards will be made to M.D. physicians and dental physicians for approximately $64,000 per investigator. A great deal of support for this program was expressed at the regional meetings.

A young physician or dentist can obtain up to 3 years of support to develop research skills at the NIH-supported General Clinical Research Centers through the Clinical Associate Program. The budget, administered by the Division of Research Resources, is approximately $3.5 million this year. But there is still an unmet demand for support of highly qualified candidates.

In the last 8 years, research training and career development are a lesser percentage of the total NIH budget. While NRSA funds have not decreased, the rest of the budget has increased.

In assessing outcomes of program participants, data show that the percentage of Ph.D.s awarded grants improves dramatically with NIH training. Another success rate was the number of M.D.s who hold academic or research positions, which again improves with NIH training. Specifically, 48 percent of the graduates in the MSTP have been awarded NIH grants, 88 percent hold academic or research positions, and 52 percent of the participants in the Clinical Associates Program have grant support, while 80 percent have faculty appointments. Data revealed a break-point of around 2.5 years of training after which it may not be significantly cost-effective to continue training.

The NRSA Program is funded by its own appropriation and authorization. The Research Career Programs, on the other hand, are funded by line items in the institutes' budgets, which means that without an increase in funds any increase in training support will cause a reduction in money available to support research grants. Similarly, within the NRSA, a shift in funds for fellowships will mean there is less money for training grants.

The other issue often discussed at the regional meetings was tuition. While the increase in tuition has been an average of 11 percent a year, the NRSA appropriation has remained essentially level. Obviously, this disparity results in fewer trainees being funded. Traditionally, the NIH has believed in the principle of full payment of costs, which would lead to fewer trainees being funded each year.

Stipends received much comment at the regional meetings as well. The NIH has instituted for FY 1989 an increase in stipends for predoctoral students to $8,500 per year and for postdoctoral fellows $17,000 to $31,000 per year, depending on the years of experience.

Discussant

Charles Brokaw, Ph.D.
California Institute of Technology

If present trends of escalating costs and a level budget continue, the number of predoctoral institutional training programs could erode to the point of existing in only a handful of the most prestigious universities in the Northeast and in California. Situations already exist where students find that being an NIH trainee is financially unattractive compared to alternatives like teaching and research assistantships. The NIH should pay an average of 80 percent of the cost for stipends plus tuition.

The proposed two-tiered tuition fee allowance plan would have the immediate effect of transferring funds from institutions with higher than average tuition to those with lower than average tuition with no increase in the number of trainees supported. Unless funds could gradually be released to support a larger number of trainees, this plan would find little support. The temporary tuition caps and cuts advocated by a plan developed by the Tuition Containment Workshop last summer were a stopgap measure, but these levels would not solve the tuition problem permanently.

Local availability of funds to supplement NIH support varies among scholarships, assistantships, and stipends. In order to maximize the effectiveness of NIH training grant funds, an increase in flexibility once funds are awarded to the institutions is required. Stipend payments from NIH funds above the established predoctoral level should be allowed with a limit set in advance.

Discussant

Rudi Schmid, M.D.
Dean
University of California at San Francisco School of Medicine

Of M.D.s who were trainees in training grants, only 7.1 percent subsequently succeeded in obtaining RO1 grant support as principal investigators. (This figure is taken from the NIH Briefing Book, supplied to the conferees.) This is an appalling figure. Trainees with at least 2-1/2 years of experience have substantially higher success rates. Little has changed since the

following recommendations on the issue were made 2 years ago: (1) examine training grants for M.D.'s to determine whether these are the best way to train individuals; (2) their duration; and (3) increase training stipends to competitive levels.

Another disturbing trend was the low number of students and house staff who choose academic careers. One possible factor is the lack of proper role models among the faculty. A significant number of trainees destined for academic careers are lost during house staff and fellowship training. This trend is particularly disconcerting, since substantial training funds have already been invested in these individuals.

The NIH response was to establish Physician Scientist and Clinical Associate Awards. These are very imaginative and promising programs, but they are underfunded and the number of trainees too low to have a major impact. Societal trends toward a more self-centered and opportunistic generation and opposition to the unregulated expansion of science my also influence career choices of the trainees.

Critical career points, such as immediately following medical school and fellowship, need to be studied to provide information on how to improve retention. Stipends must be raised to levels that are competitive with those awarded for clinical training. Finally, the Physician Scientist Awards should be increased and extended to 7 years duration.

Open Discussion

Dr. Schmid's figure of a nearly 7 percent success rate for training grants for M.D.'s was lower than the figure thought to be correct by the Committee—nearly 17 percent. The Committee also cautioned that using RO1 support as a measure of favorable outcome may discount other important outcomes, such as participation on a research team, or becoming an industry-supported researcher or an investigator conducting a clinical trial.

Citing the Marine Corps slogan of "a few good men," a Committee member suggested that the NIH take the approach of developing elitist centers of scientific excellence and funding training for only the best students. The centers of excellence established in West Germany at the Max Planck Institute have become magnets attracting the best minds in Europe to do research there. Therefore, more funding for more programs may not be the solution.

On the other hand, another Committee member supported the approach of keeping the number of programs large in order to give students the freedom of choice to select optimum training for their field. Full tuition payment is also essential for the students to choose freely the university they want to attend, rather than being limited to State or other low-tuition institutions. In addition, for the M.D./Ph.D. students, a cooperative approach should be taken to allow a student to obtain an M.D. from one institution and a Ph.D. from another, assuming the best possible combination could then be chosen. Training programs are preferable to fellowships because they provide a certain esprit de corps. The scientific community is mortgaging its future if funds for training are not emphasized. The continuous flow of young scientists must be maintained in order to capture those few who will really make a difference.

Because the competition for research trainees is stiff, the plan to increase stipends to $8,500 may still not be sufficient to attract the best students. Many universities are supplementing the stipend by 10 percent to 25 percent, so the competitive range is from $8,500 to $12,000. Another problem is the reentry difficulty for fellows. The country's medical schools are not organized to produce medical scientists; they are organized to produce physicians. After years of medical school and residency training outside of the laboratory environment, the

technology and concepts at the bench have changed. The postresidency M.D. should be able to spend 2 or 3 years in a basic science laboratory, especially given the current dominance of cell and molecular biology, to acquire skills and knowledge he or she will need to become a medical scientist.

Responding to comments on outcomes for NIH trainees, the Committee was not certain whether becoming a faculty member at a medical school should be considered a successful outcome. In terms of providing role models, this could be considered a useful outcome. Another possible successful outcome, which the NIH data may not be capturing, would be research for the pharmaceutical industry or the medical device industry. The NIH would like to count these scientists but has difficulty tracking them once they leave the training program.

On behalf of the nurse scientists, the NIH was urged to begin planning for 20 and 30 years into the future and take into consideration the changes in medicine that are already occurring today. Currently, there is a huge demand for qualified nurses, but there is little incentive for an intelligent young woman to seek a nursing career. The NIH established the nurse scientist program 2 years ago, and this program needs to be recognized and supported. The program is also important to provide role models for young nursing students in order to show them a career path to aspire to without leaving the nursing field.

Increased funding was recommended for the earlier stages of training, such as high school student programs, summer fellowships, and support for medical students to take a year off in order to have a meaningful research experience. At the postdoctoral level, increased availability of the NRSAs is also recommended, because a research track record is important in obtaining a regular grant. The NIH should target funding in these areas in order to have the most impact.

Closing Remarks

James B. Wyngaarden, M.D.
Director, National Institutes of Health

The NIH, in order to fulfill its mission, must be concerned about the health of the biomedical research institutions where the majority of the research is being performed. Indeed, with over 80 percent of the total NIH budget invested in external research funding, this year-long review of biomedical research institutions has been important and stimulating.

A number of cogent comments and proposals have resulted from the regional meetings and scientific community input to this process. A report will be prepared from the discussion of this Committee.

Jay Moskowitz, Ph.D.
Associate Director for Science Policy and Legislation
National Institutes of Health

The working group participants are asked to review their reports, prepared as briefing materials for this meeting, and make any necessary revisions as well as incorporate comments from the Committee during the discussion. A draft of the precis that will be attached to each working group report will be sent out for review to the group members. The participants at the regional meetings will then be given an opportunity to review the revised reports. From this reiterative process, a final report will be produced and will hopefully be available at the Committee's next meeting, tentatively scheduled for December 1-2, 1988. This report will initiate the development of several blueprints for the next decade.

Appendix A

Advisory Committee to the Director, NIH

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June 27-28, 1988

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June 27-28, 1988

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Appendix D

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Appendix

REPORTS OF NIH WORKING GROUPS

ON

ISSUES DISCUSSED AT REGIONAL MEETINGS

OF THE

ADVISORY COMMITTEE TO THE DIRECTOR, NIH

Report on Peer Review

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PEER REVIEW

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REPORT ON PEER REVIEW

I. INTRODUCTION

A. General Overview

The impact of the National Institutes of Health (NIH) peer review system on the direction of biomedical research in this country is widely recognized. From its inception, the peer process for review and approval of grant applications has been the subject of considerable attention and numerous studies. NIH recognizes the importance of continued surveillance to ensure that the system functions well and remains responsive to the needs of the public health, the biomedical research community, and the NIH.

B. History of Peer Review

The concept of peer review dates back to the late 17th century, when the Royal Society of London established a board of editors to evaluate reports submitted for publication in its Proceedings. Peer review procedures for that portion of health research in the United States supported by the federal government were initiated in 1902. At that time, the 57th Congress established a scientific advisory board of nongovernmental scientists to assist the Surgeon General in the administration of the Hygienic Laboratory, which was renamed the National Institute of Health in 1930. This advisory committee was later reconstituted and renamed the National Advisory Health Council.

In 1937, when the National Cancer Institute was established, the Cancer Act provided a legal basis for the National Advisory Cancer Council. These authorities and procedures were extended to grants and fellowships in all health research areas, when the Public Health Service Act was passed in 1944. In 1946, the NIH Director established the Division of Research Grants (DRG), and study sections or initial review groups (IRGs) came into existence. This was the beginning of the NIH extramural programs and the current peer review system.

The NIH Executive Committee for Extramural Affairs (ECEA) was established in 1950 and given general responsibilities relating to review and advice concerning all NIH extramural policies and procedures. Formal separation of extramural program staff from review responsibilities occurred in the 1970s. In 1979, the ECEA was reorganized to serve a more coordinative function and was renamed the Extramural Program Management Committee (EPMC). The EPMC, which consists of a chairman from the Office of the Director, NIH, and a senior extramural program staff person from each Bureau, Institute, and Division (BID), continues to this day.

Until the early 1960s, research support was relatively generous and the top 90 percent of approved applications was usually funded. As funding resources became more limited in the mid-1960s, it became more urgent to identify and assess issues raised about the peer review system and to resolve any problems. Many of these same peer review issues are still relevant. In general, they have been discussed widely by the Executive Office of the President, Congress, other branches of Government, interested professional and other organizations,

and the scientific community. Over the years, studies of the NIH peer review system have been conducted by several external groups. A number of Congressional committees (Baynes-Jones, Elliott, Wooldridge, Westrate, Ruina, Rogers, Whittaker, and Fountain) have examined the operational and administrative aspects of NIH peer review, studied the recurring issues, and documented the strengths and weaknesses of the system. Several major changes have resulted from their recommendations.

Because NIH realized the need for continuing overview of the system, in April 1975, the NIH Director established a 14-person Grants Peer Review Study Team to conduct a detailed and comprehensive study of the NIH peer review system. The Study Team held three public hearings, invited written comments from 37,000 people, and asked review committees and council members to complete a survey questionnaire. In January 1977, the Study Team submitted its three-volume report (which contains 69 recommendations) to the Director, NIH. One of the Study Team's main recommendations was that a single convention be utilized to report a study section's assessment of scientific and technical merit. (Some BIDs had been using a system of standardizing priority scores across study sections through the use of a normalizing process and/or percentiles.)

In 1979, the NIH Director set up the Review Policy Committee (RPC) composed of the chiefs of the review sections for all the Institutes and Divisions that have an extramural review function. This committee remains in existence today and is the principal trans-NIH forum for the development, implementation, and evaluation of review policies and procedures for research, training, and career development awards. An NIH Priority Score Work Group, established in 1983, identified the potential problem of drifting scores, which is still apparent to the RPC today.

The priority scoring issue, among others, was not easily resolved. Most BIDs (10) now use percentile scores as the principal indicator of study section assessment of scientific merit. This involves 83 percent of the applications reviewed.

In June 1987, the NIH Director formed the NIH Peer Review Committee, charged with the task of continuing to assess the system, discuss the recurring issues, and recommend possible changes, as necessary. This committee has requested comments from Council members, members of the scientific community, and BID directors and staff. Concurrently, at least three other groups have studied various aspects of peer review: the Receipt, Referral, and Review Committee (3R); the Working Group on the Movement of Priority Scores (WGMPS), which was a subcommittee of the RPC; and the Triage Working Group, another subcommittee of the RPC.

C. Overall Summary of Public Testimony

Review issues raised by the research community as early as the mid-1960s have involved support of innovative research and the relative emphasis on the investigator's accomplishments or research project, administration of review, qualifications and selection of reviewers, and the review process itself. At a series of seven regional meetings conducted by the Advisory Committee to the Director, NIH, from October 1987 through March 1988, these issues emerged

repeatedly in public testimony as subjects of continuing interest and concern. The meetings encouraged critical comment and thoughtful recommendations.

While citing areas of the process perceived to need improvement, almost all speakers applauded peer review and the NIH system in general terms. The NIH peer review system was called "the best of any federal agency" and "with all its flaws. . .the best, by far." It was stated that peer review is "a particularly effective mechanism for evaluating scientific merit of research grants" and that it "has been a central element in assuring the quality and excellence of the research supported by the National Institutes of Health and should continue to be the basis for all funding decisions." One public witness seemed to represent the views of many with the following comment: "Despite personal difficulties with the peer review system. . .I believe it remains the single best method of assuring close monitoring of productivity and encouragement of the sustained aggressive pursuit of research."

Details of concerns and suggested changes are included in the following sections of this report.

II. DISCUSSION OF PRINCIPAL ISSUES

A. Philosophy of Review

1. Statement of the Issue

The research that NIH supports as a result of peer review and subsequent funding decisions has always been of paramount importance. An issue that recently received increasing attention is whether research project grant applications for support of innovative research are reviewed in an appropriate manner and receive priority ratings that are equitable. A separate but related issue is the relative emphasis given to the past productivity of the investigator and the proposed research project during peer review.

2. Background

The philosophy of review has undergone several changes in emphasis over the years, although the six criteria identified in Federal regulations have been used since conceptualization of the NIH review process. When NIH programs were smaller and their content was known to most experts on study sections conducting scientific merit reviews, the qualifications and experience of the principal investigator and the staff were salient features in assigning priority scores. Indeed, when the past record of the investigator was exemplary, even though the proposed research was described in rather broad terms, a highly favorable score would be assigned. It was assumed that the investigator's past success would guarantee further progress. In those times, almost all of the favorably recommended applications were funded. By the 1970s, when the number of applicants had increased dramatically and included many new, younger investigators, reviewers placed greater emphasis on the written application, the details of the proposed project, and the background information that demonstrated the investigator's knowledge of the field and methodologies. In the late 1970s, the small grant mechanism was developed to provide at least modest support for several purposes, including the collection

of pilot data for innovative ideas as justification for subsequent research project grant applications. The Biomedical Research Support Grant also has been used for this purpose, although less so today due to funding constraints. More recently, growing concern has been expressed about whether the review process provides adequate priority scores for innovative approaches that depend more on future than past achievements.

3. Views of Public Witnesses

In meeting after meeting, speakers stated their belief that the current peer review system encourages projects that have little or no risk of failure. It was felt that a bias exists in favor of the current mainstream of research and accepted methodology.

One problem, frequently noted, was that reviewers are unable to predict the success of new lines of research and, therefore, tend to rate innovative research lower than more predictable, well-established approaches. Some acknowledged that it is difficult to distinguish the unorthodox from the creative and innovative. This bias, in turn, encourages investigators to opt for "safe" projects in lieu of more innovative studies. Speakers were of the opinion that part of the difficulty in developing an adequate balance between innovative and more established types of research is a peer review system that perpetuates sameness. Some believe that peer reviewers have vested interests in the outcome and preservation of the status quo of research subjects and methodology; that they are not neutral parties; and that, to cope with the growing number of applications, study sections have tended to be more superficial and technical in their evaluation criteria. This influences the applicant to focus on grantsmanship rather than innovation. For young investigators, success is becoming dependent on their ability to respond to bureaucratic demands and adapt to scientific fads. Concern was expressed that, as scientific disciplines "fall from favor," this can lead to depopulation of active researchers in important fields, such as physical organic chemistry. It was noted that panels with younger scientists have a tendency not to recognize the record of performance of even the most outstanding investigators. NIH was urged to modify the review system to ensure that new ideas receive an adequate unbiased evaluation, especially when projects are multidisciplinary, and to give more emphasis to the investigator's record of accomplishment.

It also was suggested that NIH augment the peer review system by providing lump sums of base funding to universities and research institutes as an incentive to venture into new fields, and provide special funds earmarked for creative, innovative research. Speakers also recommended that a special study section be convened to review applications with innovative ideas. When applying for special innovative research funding, principal investigators could check a box on the face page or otherwise identify the grant application as one involving innovative research and justify such designation in a descriptive paragraph. Special review criteria should be developed for innovative research grants; for example, the investigator's record in conventional investigations as well as creative contributions, evidence of keen insight into a problem, how questions are framed, and ingenuity of approaches.

Speakers proposed that study section procedures be modified to ensure earlier identification of any additional information needed on an innovative grant application, so that it could be obtained prior to the study section meeting, and thus minimize the need for reapplication. When evaluating grant applications, equal emphasis could be given to the record of the principal investigator over the previous five years and to the project. Quality, not quantity, of publications should be reviewed in-depth.

A need was identified for a retrospective study to correlate scientific bibliographic citations with priority scores, and a prospective study of study section ratings and their ability to predict research significance and likelihood of success.

4. Status of NIH Activities

NIH is responding to the scientific community's concern about obtaining support for innovative research and increasing the emphasis on the record of the investigator.

- An NIH study has been designed to assess the feasibility and effects of a newly weighted, three-element paradigm (concept, investigator, protocol). In this study, current review criteria have been revised and weighted to alter the balance in emphasis from primarily a project orientation to one that gives greater weight to the investigator's record and to innovative ideas.

5. Options for Consideration in Addressing Issue

NIH recognizes the need to continue to evaluate the ability of the peer review process to identify and review objectively innovative research, and to apply appropriate emphasis to the record of accomplishment of the applicant. Options suggested for consideration include:

- Special study sections could review innovative research applications.
- Specific limited funds could be designated for new or innovative concepts approved by study sections.
- Extended grants could be considered for investigators with outstanding records to conduct innovative research and provide long-term stability and support.
- Deliberations and new approaches within Councils and BIDs may be necessary to identify and support more innovative research.
- Increased use of the small grant mechanism as well as the Biomedical Research Support Grant for pilot studies of innovative ideas.

B. Administration of Review

1. Statement of the Issue

This topic refers specifically to the workload for both reviewer and investigator that is associated with the peer review system. Major factors contributing to growth of the workload over the years are increases in the length of applications and summary statements, increases in the number of support mechanisms, and ever larger numbers of grant applications and amended applications. Concerns also have been expressed about the impact of this increasing administrative burden on the appeal of research as a career to promising young scientists as well as on the creativity and productivity of established investigators. Another Working Group is addressing this overall issue from the standpoint of "Flexibility and Continuity of Research Funding."

2. Background

Early in NIH history, research project grants were awarded for seven years, but duration of support was reduced to five years during the 1960s to ensure better accountability relative to both scientific and administrative management. By the 1970s, more and more research project grants were awarded for three years or less because of growing concern about limited resources and accountability. At the same time, there was a growing demand by reviewers for more information about each proposed project. As a result, applications became longer, included more appendices, and more supplemental materials. This, coupled with an increase in number of both new and amended applications, had a dramatic impact on the workload of peer review. The number of amended applications began to increase during the 1970s and reached 27 percent of all applications received at NIH in 1986. Aware of the increased competition for funds, that year 17 percent of applicants submitted more than one application. An additional impact on the workload and complexity of review was the marked increase in NIH support mechanisms over the years and the growth in BID reviews, especially for solicited programs. When summary statements from the review became available to the investigator, as a result of the Privacy Act of 1974 (P.L 93-579), there was also a mounting need to provide additional information and feedback to the investigator, especially for unfunded applications. Reviewers began to write longer, more detailed review comments, which increased their workload. Executive secretaries struggled under this burden of longer applications, a greater number of applications, and copious review notes. Finally in the mid-1980s, PHS issued guidelines for page restrictions for research project grant and multiproject applications. Today, applications that exceed the prescribed limit are returned to the investigator by the Division of Research Grants.

3. Views of Public Witnesses

The administration of the peer review system was a frequent topic for comment at the presentations around the country, and many suggestions for improvement were offered. According to numerous speakers, the extensive grant application process places researchers in a "Catch-22" situation. If researchers want to continue to expand their research, they must devote much of their time to applying and reapplying for grants, which, in turn, takes them away from research. Although the specific logistics that were discussed varied, the

speakers' central theme was the need to streamline the process of grant application and review. By far, most often mentioned were what speakers termed the excessive "red tape"--paperwork and time--involved in grant applications and the instability that results from brief funding periods. It was estimated that, in some circumstances, as much as 40 percent of a researcher's time may be spent applying for grants, time the speakers contend would be better spent in the research laboratory.

Among numerous suggestions for streamlining the application process was a proposed approach that would eliminate the requirement for a totally new application when a prior application has been approved but unfunded, substituting instead a simple rebuttal of critique, plus any additional relevant information. When a study section reviewer misinterprets part of an application or a difference between the reviewer and the applicant arises, the applicant should be encouraged to reply only to the pink sheet critique, which could then be considered at the next session of the study section. This process could shorten the time for review as well as decrease the review load.

Another suggestion to save applicant and reviewer time was to reduce the number of publications presented in the application's bibliography to only two well-thought-out and comprehensive publications per year. Fewer and better quality publications may result and reviewers would be better able to judge the contributions of each paper because their workload would be reduced.

Many speakers cited short funding periods as one reason so much time is spent on grant applications. It was noted that cyclical funding of ongoing projects and programs, which often results in months of delays and interruptions in support, is "the most vexing problem" of the peer review process. Several speakers said that, as a consequence of short funding periods, nearly all laboratories maintain at least two grants, to ensure that there is a buffer in case one grant is terminated. Although this practice doubles the workload of both the researcher and the study section, researchers feel they must apply for these grants as "insurance" to protect themselves and their staff.

Several speakers suggested that all grants be awarded for at least five years, with annual or biennial review by a competent panel to ensure that the project is active and making progress. It also was suggested that the last year of funding be distributed over two years to reduce the workload of the scientists and reviewers, and that NIH provide interim support of projects when a renewal is not funded on first submission and the application is being revised and resubmitted. Several speakers also recommended that funds unspent at the end of the year be allowed to be rolled over to the next year.

Other problems identified by speakers involved aspects of priority scoring of applications. Because many new applications are in the priority range just beyond the payline, often somewhere between the 25th and 40th percentile, NIH should consider mechanisms to provide at least partial support for some maximum time period.

Another concern expressed was the potential problems with the new page restrictions for grant applications, which could be disadvantageous for both new and experienced investigators. With shorter applications, the researchers'

record--something new investigators may not have established--may become more important, thus putting new investigators at a disadvantage. On the other hand, experienced investigators may have a restricted opportunity to describe fully the progress made during previous funding periods.

Finally, suggestions were made that NIH pursue, as soon as possible, electronic communication for processing and review of grant and contract applications in order to reduce the administrative burden.

4. Status of NIH Activities

NIH recognizes that a problem exists with regard to the administrative burden of review and several review procedures and guidelines are now being streamlined:

- The research grant application process has been simplified by restricting the number of pages in specific sections, e.g. experimental design and methods section.

- Discussions with reviewers and NIH staff have encouraged changes in attitudes and behavior in order to minimize the perception that excessive documentation is necessary.

- The Florida Demonstration Project offers the potential of streamlining reporting requirements associated with grants administration. As the demonstration expands, the grant application process, both in terms of content and electronic transmission, will be examined to identify potential simplification.

- An NIH study currently is evaluating the impact on workload of reviewers and DRG staff of a newly developed, structured reviewer's form, and a modified, shortened summary statement.

- Another study is evaluating the preparation of a combined summary statement (COSS) for review of selected amended applications. This new summary statement focuses on the revisions that have been made to the prior application, includes the study section recommendations, and is attached to the previous summary statement.

- An NIH evaluation is underway of a process to triage solicited research project applications by having a peer group prescreen them for assignment to an in-depth or abbreviated review based on competitive status.

- Faster and simpler ways of electronically transmitting applications, reviewers' comments, and summary statements are being developed to streamline the process and expedite review.

Another approach to dealing with the administration of review has been to increase the duration of the research grant award. In 1987, the average length

of award had increased to 3.8 years from 3.15 years in the late 1970s. In addition, two new special NIH awards recently were initiated:

- o First Independent Research Support and Transition Award (FIRST) which provides five years of support to newly independent investigators.

- o Method to Extend Research in Time (MERIT) awards offer funding up to ten years to those outstanding investigators likely to continue successful and productive research.

The Javits' Award of NINCDS and the Outstanding Investigator Grant (OIG) of NCI are ongoing programs developed to increase the duration of research grant awards. The OIG was the first of these awards and was developed in response to issues raised to the President's Cancer Panel in 1982. It has a number of special features, including seven year duration, early reapplication in the fifth year, automatic carryover of up to 20 percent of grant funds and more if requested, and review of the application based entirely on the record of the investigator.

5. Options for Consideration in Addressing Issue

Additional appropriate steps to limit the administrative burden of review may be necessary. One of the most pressing issues is the proliferation of amended applications. As the number of unfunded applications has increased, the number of revised applications, and of multiple applications from the same investigator, has grown. Several options to address this concern are under consideration:

- o Develop a way to identify revised sections of the amended application.

- o Triage amended applications with return of those inadequately revised.

- o Focus review on revised sections of the application and integrate current critique with previous review comments.

- o Limit the number of amended versions of an application that may be submitted.

- o Consider the submission of supplemental material in letter form for review with the original application in lieu of a complete amended application.

C. Reviewers

1. Statement of the Issue

The changing nature of science and the increasing competition for research funds have focused attention on those who review grant applications. Issues related to the qualifications of reviewers, methods by which they are selected, composition of study sections, and assignment of applications to appropriate study sections and reviewers are discussed in this section.

2. Background

The Division of Research Grants (DRG) was established in 1946, when extramural biomedical research activities were moved to NIH. At that time, 21 study sections were set up to review grant applications. These study sections reflected the state of the science, e.g., malaria and venereal disease, and each consisted of 15-16 non-federal experts who met to discuss the research proposed. During the early years of NIH extramural funding, reviewers could serve on two to three study sections simultaneously, and several reviewers from the same institution could be members of the same study section. Changes occurred in the system as the types of research evolved and the number of applications grew throughout the 1950s and 1960s. Potential reviewers were nominated, as they are today, by the executive secretary of the study section in which a vacancy existed and appointed by the Director, NIH. Nominees were selected on the basis of many factors that related primarily to the outstanding abilities and accomplishments of the individual as viewed by peers. Terms of service were four years, and rules were developed for reappointment. In the mid-1970s, the Public Policy Committee conducted a study to determine whether the peer review system was operating as a "self-perpetuating oligarchy." Results indicated that the distribution of reviewers from geographic and institutional standpoints was equitable (Science 1975; 198:204-205). In the 1960s, applications were assigned to study sections and to BIDs based upon the knowledge and experience of two DRG staff members. Today, 68 chartered DRG study sections exist, some with subcommittees that meet regularly and separately, for a total of 92 groups. These groups represent a total of about 1,500 reviewers. Each standing study section's charter defines its review responsibilities, primarily on the basis of scientific disciplines; within these, emphasis may change as reviewers and the state of the science changes. Today, assignment of grant applications follows written NIH referral guidelines, which are updated every 2-3 years.

3. Views of Public Witnesses

In the public forums, comments about reviewers were addressed primarily to their expertise in relation to the scientific emphasis of the study section, and the procedures used to select study section members. Some speakers questioned whether reviewers always had the expertise to evaluate the grant applications within their purview. Moreover, the fact that as few as two reviewers might have the expertise needed to review a given grant application could adversely affect its priority score. Also of concern was whether the expertise of existing study sections was appropriate for review of the increasingly frequent interdisciplinary research applications. Study sections may not be adequately constituted to assess complex data sets that are now available and are often part of proposed research.

It was recommended that the composition of study sections be altered to increase representation of minorities; geographic regions; more M.D.s; and certain disciplines deemed critical to a knowledgeable evaluation of grant applications for interdisciplinary and new lines of research. Numerous speakers suggested including a broader spectrum of specialties, particularly veterinary medicine, diagnostic radiology, engineering in medicine, the

behavioral sciences, nursing research, and nutrition (with a biochemical emphasis).

Also noted was the difficulty in securing qualified reviewers. However, as a result of enhanced communication efforts on the part of DRG, the refusal rate, based on letters of invitation, has dropped from about 12 percent in FYs 1985 and 1986 to 6-7 percent in FY 1987, and from 20 to 10 percent respectively for women. M.D.s decline to serve more frequently than Ph.D.s and also resign more frequently without finishing their terms. It is, however, recognized that the commitment involved in accepting a study section assignment is considerable because it involves about 2 months per year in reviewing applications, mostly on evenings and weekends, and reviewers are compensated only for their time spent at committee meetings. It also was noted that investigators may be reluctant to serve on a study section that would customarily review their own applications, because their applications might go to special study sections (SSS). These groups may be perceived to be less qualified. In addition, the resultant percentile values would be based on the SSS priority score and its corresponding percentile for all DRG study sections rather than just one regular study section.

Among comments about the process for selection of study section members were that it reinforced the appearance of "cronyism", leads to what was described as "inbreeding", and results in more poorly qualified reviewers.

To address these concerns, it was strongly recommended that a current study section not determine the composition of the next one, and that scientists who receive good priority scores on their grant applications be invited for membership. Speakers emphasized the importance of the scientific knowledge of reviewers and some suggested trial membership to assess an individual's objectivity. Other speakers suggested that an entire study section review the curriculum vitae of potential candidates and express their personal knowledge of the candidate's objectivity and expertise. NIH was urged to improve communication with smaller medical schools, and include their faculty members on study sections more often. This would have the dual benefit of reducing the inbreeding cited and redressing the underrepresentation of these institutions in the NIH peer review process.

A number of comments identified the need for uniform guidelines for reviewers. Further, it was stated that, although peer review is the best method to monitor productivity and encourage research, the process can be improved by informing applicants about the changing expectations of study sections regarding grant application content, particularly the need for preliminary results for each proposed technique or project.

4. Status of NIH Activities

Since the mid-1960s, when the number of applications competing for funds increased markedly, concerns have been raised about the qualifications and

selection of reviewers. NIH has introduced several procedures to address these concerns, and additional ones now being implemented are highlighted below:

- An NIH evaluation of different types of review modes is underway, e.g. mail review, (see Review Process) to assess the potential interactions and dynamics of the review process.

- A report is in preparation to raise the awareness of the scientific community of the obligation to serve on study sections. It will be presented for comment at a meeting with members of the scientific community and then widely distributed.

- Prior to being appointed to a study section, virtually all new members have been "tested" by serving as an ad hoc reviewer.

- NIH recently announced and encouraged applicants to suggest study section assignment. Applicants may identify up to three study sections which they believe are most suitable for the review of their applications.

- An examination of trends in study section representation of various groups has revealed that:

  the average age of study section members, which is about 45, has remained rather constant over the years;

  minority representation on study sections is now 15 percent, which is more than double the 5.7 percent in 1976; and

  although the proportion of M.D.s on study sections is declining (their refusal rate is high), it remains about 35 percent and that is higher than the approximate 30 percent of M.D. principal investigators on the R01 applications they review.

5. Options for Consideration in Addressing Issue

Among suggestions proposed to effect further improvements in reviewer issues are these:

- Improvements in the selection and training procedures for reviewers and for executive secretaries, who are responsible for recruiting new reviewers and ensuring the quality of the review process, could be considered.

- Extension of ongoing grants and, in certain cases, long-term administrative support could be provided to grantees who serve on study sections.

- Special shorter terms of service for senior investigators as well as possible other roles, such as a more statesmanship function without specific review assignments.

- Applicants could be requested to recommend reviewers for their grant application.

- Evaluation could be conducted of the ability of study sections to review grant applications proposing multidisciplinary research, or using new approaches such as molecular biology, to address an organ-related question.

D. Review Process

1. Statement of the Issue

Throughout its history, the peer review process has undergone changes in response to identified needs. Doubling of the number of new and competing research project grant applications reviewed over a period of the past 16 years (7,570 in 1970 and 15,858 in 1986) has presented a challenge to use the peer review system more efficiently. One suggestion under consideration is greater use of mail review. Another challenge relates to study section scoring behavior because, during the same period, applications favorably recommended increased from 70 to 90 percent, and scores within the 100-175 priority score range increased from 22 to 36 percent. Concern has been expressed about the scoring system because applications with good priority scores are not being funded.

2. Background

As mentioned earlier, the NIH-wide peer review process, which resides in the Division of Research Grants (DRG), utilizes chartered study sections with designated areas of expertise. Members of these study sections meet as a group to review applications at regular intervals each year. When applications assigned to a regular study section require special expertise, the need may be met by inviting ad hoc reviewers to attend a regular study section meeting or by obtaining supplemental assessments through mail review. In instances where no regular study section has the required expertise and several applications are involved, a special study section may serve as an ad hoc review group. Approximately eight percent of the applications reviewed in DRG are reviewed by such tailor-made review groups. Furthermore, in 1987, DRG examined the experiences of eight "fundamental" study sections to learn the extent of use of ad hoc reviewers or mail review. At a total of 24 meetings held by these regular study sections, an average of six ad hoc reviewers were present at the meetings to advise the study section members. In addition, of 1900 applications reviewed by the eight study sections, 146 (7.7%) utilized mail reviews to obtain opinions by other experts.

In its earliest years, NIH fiscal resources were sufficient to fund the top 90 percent of research applications approved by a study section. It was not until the early 1960s that growth in NIH programs dictated the need for more selectivity. Priority scores did not assume their present importance in funding decisions until the late 1960s. In 1967, however, the National Advisory Heart Council became concerned that reliance on "raw" priority scores might result in inequities and program imbalances. The Council recommended, therefore, that the raw priority scores be normalized so that ratings assigned by different study sections would be more comparable. By 1979, this adjustment procedure was being used by six Institutes, namely NIA, NIAID, NICHD, NCI, NEI, and NHLBI. Normalization utilized a statistical procedure to adjust the raw score to a Gaussian (i.e. normal) distribution, although the sequence of

priority scores assigned by each study section was retained. In January 1980, however, the NIH Director determined that raw scores should be the NIH-wide criterion used to reflect the ratings of study sections. Shortly thereafter, several BIDs began to use the current modification, known as percentiling. Percentiling provides information about the relative position of an application within a specified comparison group. In most instances, the comparison group is a single study section. However, for applications assigned to study sections that reviewed less than 15 applications in the current round or less than 25 applications in the last two rounds, the comparison group is the total of all DRG study sections. Percentiling does not extend to RFAs, programs with set-aside funds, Center grants, training and manpower programs, and career academic awards.

3. Views of Public Witnesses

During the public forums, comments about NIH peer review frequently touched on the review process per se. As already noted, there was a perception of bias within the system.

Another problem cited was the assignment of applications to only one or two primary reviewers. It was suggested that there be an increase in the number of primary reviewers, perhaps three or four. It was noted that unfunded "low" priority scores of greater than 150 are not statistically different from 152 or even 180, when recommended by only two primary reviewers. Recommendations to improve the process included adding more reviewers to study sections, computerizing the process, shortening the application forms, and providing more long-term funding.

Although the scientific quality of reviews was generally considered good, the scoring was deemed to be arbitrary in many cases. Among problems cited was the possibility that one strongly negative vote might exclude an otherwise meritorious application from funding. To minimize this possibility, it was suggested that NIH exclude the highest and lowest scores from the averaging of priority ratings. Also questioned was use of the scores from the previous three study section meetings in calculating percentile, because this might be inappropriate if dramatic changes in quality of applications occur at any one meeting.

There was concern that new page restrictions for applications seriously reduce the information available for review of experimental design and procedures, encourage safer ideas, and increase appendices (see Administration of Review section for additional discussion). The new format also may "risk the keystone of peer review"--an application that can be evaluated for scientific merit and the likelihood of success. Caution was urged in attempts to streamline the review process. It could become too abbreviated and superficial resulting in reduction or elimination of constructive feedback to investigators, particularly young researchers.

There was the perception that deterioration in scientific background among the new generation of executive secretaries in DRG is contributing to lower quality summary statements, which are seen by some as increasingly inaccurate, undocumented, and to understate criticisms. They frequently contain the

opinions of only one reviewer rather than a summary of the entire discussion that resulted in the assigned priority score. More comprehensive pink sheets were suggested, which might also discourage submission of a revised application, that receives the same criticisms and similar score, because the applicant has not been informed about all criticisms.

Although the long review process is admittedly a problem for investigators, some speakers expressed concern with attempts to circumvent the peer review process through legislative action. NIH should consider distributing funds equitably to large research centers and smaller institutions. Scientists in general are dismayed that colleges lobby Congress to pass legislation that will award them funds for science development instead of seeking support through peer review.

Speakers offered diverse views of the system. One stated that "the genius of the NIH system has been the combination of investigator-initiated applications and peer review", and felt that trends away from the combination would slow future progress. Another, however, stated that peer review had outlived its usefulness, was inequitable, discriminating, and unfair, and suggested alternative funding mechanisms. Some believe that peer review discourages new ideas, favors selected institutions and geographic regions, discourages young scientists, and helps erode the edge in technology worldwide. It was proposed that NIH fund grants via formula or per capita through contractual arrangements with institutions and cap funding to single investigators.

Among numerous specific recommendations for improving the peer review system, was that the study section process be evaluated and results be communicated back to investigators.

4. Status of NIH Activities

The peer review process has become much more complex due to such factors as increased competition for funds and the rapidly changing nature of biomedical research. The matter of scoring has been addressed widely within and outside NIH. At issue are the differences in study section scoring behavior, the use of percentile vs. priority score, and "priority score creep." In response to this issue and the need for simplification, clarification, and more efficient use of resources, NIH has undertaken several activities:

- An NIH study is planned to evaluate the characteristics of various models of mail review as compared to the traditional study section meeting review to assess its potential for increased utilization in the peer review process.
- NIH is assessing various approaches to expediting the peer review process.
- Aspects of the quality control of the peer review process are under scrutiny by NIH.
- Video tapes of the peer review process are being prepared for educational purposes.

- In October 1988, the use of percentiles as a basis for funding decisions will become NIH-wide.

- An NIH study is evaluating the current peer review priority score system and the use of different scoring increments, 0.5 vs. 0.1, to combat "priority creep" and provide greater separation of scores for use when making funding decisions.

- "Readers" now are assigned to review applications in addition to the two or three study section members who are primary reviewers.

- Study sections now receive feedback concerning voting patterns and priority score distributions.

5. Options for Consideration in Addressing Issue

Additional suggestions for changes in the peer review process include:

- Evaluation of the number of primary reviewers on each application needed to provide necessary expertise, particularly for multidisciplinary research.

- Enhanced use of electronic communication during the peer review process.

- Development of an ongoing system for monitoring and evaluating the peer review process.

- Expanded use of ad hoc reviewers and of mail review to supplement study section review.

III. CONCLUSIONS AND SUMMARY REMARKS

A. Philosophy of Review

While the concept of peer review continues to receive strong support from the research community, there are two aspects of the current system that are the subject of concern. One is the perceived inability of innovative research applications to receive favorable reviews and funding. The current system is said to encourage projects with little risk of failure and is biased in favor of the prevailing mainstream of ideas and accepted methodology. The other cause of concern is a limited consideration of the research record of applicants. Both of these concerns already are being addressed by the NIH study of a three-element paradigm for review (concept, investigator, protocol) and the longer-term NIH awards are freeing new and established investigators to pursue innovative research. A number of options have been suggested for stimulating funding of innovative research, including a special study section for such investigator-initiated applications, specific designation of funds for support of innovative research and increased use of small grants and of the Biomedical Research Support Grants for pilot studies which offer the twin advantages of ease of implementation and high probability of success.

B. Administration of Review

As it is presently administered, the peer review process is viewed as being unduly cumbersome and burdensome. With short funding cycles, investigators find that an inordinate amount of time is devoted to preparation of applications and reapplications to continue or expand their research activities. One option that received support and is currently under consideration is electronic communication of applications, reviewer comments, and summary statements. The technology is reliable and widely available so that efforts toward this end could be accelerated. Another suggested option which offers the prospect for significant reductions in the administrative burden of review is simplified submissions for revised applications. By only requiring revised applications to address the identified deficiencies of the original application, reviewers would be able to determine quickly whether they are sufficiently well addressed to justify a careful reconsideration. While there was testimony in favor of reducing the application-associated burden by establishing a minimum award term of five years, little reduction would likely be realized beyond what has already been accomplished through the general extension of award terms and the establishment of the longer-term award mechanisms.

C. Reviewers

Implicit in the concept of peer review are the notions first that peers can be identified and agreed upon, and second that peers will participate in the reviews. Public witnesses expressed concerns about both of these aspects of the current peer review process. Many witnesses questioned the availability of adequate expertise in selected scientific areas given the increase in interdisciplinary research. Allowing applicants to suggest appropriate study section assignments and use of ad hoc reviewers should do much to alleviate this concern. An evaluation should also be conducted of the ability of study sections to provide an adequate review of interdisciplinary proposals. The allegation of "old boy network" and "cronyism" in the selection of reviewers is more difficult to address. Further study of this concern is needed to identify new approaches for identification of reviewers.

It is recognized that service on a study section currently entails a substantial commitment. Efforts to raise the awareness among the community of their obligation to serve may have some effect on increasing the rate of participation, but it is likely that efforts to reduce the burden on reviewers will be more productive. Among the disincentives noted by public witnesses was the reassignment of grant applications from study section members to other study sections. By extending the term of grants for grantees who serve on a study section or limiting terms so that they will end prior to scheduled competitive renewals, much of the need to reassign applications could be eliminated.

D. Review Process

While a number of concerns about the review process were identified, many comments focused on the need for more effective use of resources in response to increases in workload and for improvements in the scoring of applications.

Several NIH activities relevant to these concerns have been implemented and others are under evaluation. It was noted that, with the number of primary reviewers limited to two, there was a strong likelihood that individuals could exert undue influence on the score. The degree to which such mismatches between subject matter and reviewer occur and the ability of additional readers and ad hoc reviewers to prevent them should be evaluated. With the NIH-wide adoption of percentiling and continued efforts to induce greater separation in scores, it is less likely that one inordinately high or low score will significantly influence the relative ranking of an application. Feedback on previous voting patterns and score distributions may also help to improve the reliability of scores, but immediate feedback on relative ranking of applications may be more useful. The scoring performance of the review process should continue to be subject to ongoing monitoring and evaluation.

ADVISORY COMMITTEE TO THE DIRECTOR, NIH

REPORT OF WORKGROUP ON

RESEARCH RESOURCES

JUNE 1988

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ACD Report - Resources

June 27-28, 1988
Conference Room 10, Building 31-C
Bethesda, Maryland

I. Introduction

A. General Overview

Testimony at the several regional meetings dealt with the multiplicity of research resource needs of the biomedical research institutions e.g., facilities, equipment, clinical research, laboratory animals, biomedical research support grants, human cells and tissues and research manpower needs especially among minority groups underrepresented in biomedical research careers.

This report will focus specifically on Biomedical Research Support Grants, clinical research resources including the General Clinical Research Centers and human cells and tissues needed for research.

The major issues contained in the testimony follow:

1. That the Biomedical Research Support Grant Program be continued and enlarged. The Program meets institutional needs not served by other sources of research support and as such is a unique and critical resource. Witnesses testified that the need for and value of this program's support far exceeds its current funding capabilities.

2. That opportunities for the conduct of clinical research, career development for physician-scientists and funding of clinical research facilities must improve to ensure the resources necessary to meet the Nation's need for clinical research.

3. That limiting access to human cells and tissues impedes progress in biomedical research and that fetal tissues, in particular, are especially valuable in studies of chronic diseases such as diabetes and Parkinson's disease.

B. History of the three areas of concern:

1. Biomedical Research Support Grants
The Biomedical Research Support Grant (BRSG) Program was established as a result of an evolving set of needs experienced by institutions engaged in Federally supported health-related research. Institutions involved in project-oriented biomedical research experienced problems:

--meeting emerging research opportunities
--exploring new/high risk ideas
--responding flexibly to unexpected local research needs and opportunities.

The rationale for the program was to extend opportunity and responsibility to scientific administrators to meet specific institutional on-site biomedical research needs. These funds were to assure that a portion of NIH's support for biomedical research went to institutions to use in ways and for purposes that they deemed effective in fostering their biomedical research capabilities.

First presented as a suggestion from consultants to the Secretary, DHHS (then, DHEW) in 1958, and again to the Senate Committee on Appropriations in 1960 by a separate group of consultants (Boisfeuillett Jones Committee), the Biomedical Research Support (then General Research Support) Program was presented as an amendment to Section 301(d) of the Public Health Service Act, to make grants-in-aid for the general support of research at public and non-profit institutions. The overall objective of the Program was to allow:

> "...schools to meet emerging opportunities in research, to explore new and unorthodox ideas, and to use (these) research funds in ways and for purposes which they (the institutions) in their judgement, feel would contribute effectively to the furtherance of their research programs..."

Statutory authority for general research support was established in 1960 under Public Law 86-798 which amended the Public Health Service Act to authorize "grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research and research training programs." This authorization led to the establishment in 1962, of the General Research Support Program to provide general research support to health professional schools.

In 1965, on the recommendation of the appropriations committees of the Congress, the Biomedical Sciences Support Grant (BSSG) Program was established to provide institutions, other than health professional schools, with general research support similar to that of the General Research Support Program.

After a period of separate operation, the two programs were merged to create the Biomedical Research Support Program in 1976. The Congress concurred in this action (House of Representatives Report No. 94-311: Senate Report No. 94-366). At this time a single award computation formula and

eligibility criteria were established and applied equally to all applicant institutions.

The BRSG Program strengthens and enhances the research environment of institutions heavily engaged in health-related research. Local decisions on the use of these flexible funds enhance the efficiency and efficacy of institutional biomedical research capabilities.

In 1987 the BRSG program funded over 8,000 projects at 594 institutions. Supporting pilot studies, new investigators, centrally shared equipment, interim funding and unexpected or emergency requirements.

The original authorization for BRSG limits the appropriation for BRSG to 15 percent of the funds available for NIH research grants. This level has never been reached. The appropriation for BRSG peaked at 8.5% of NIH's research dollar base for grants in FY 1969 and attained its lowest level (1.2%) in FY 1988 (See Table 1). During this same period the average Research Project Grant award increased by 195% while the average BRSG award increased 4%.

2. Clinical Research

In FY 1960, responding to a Congressional directive, NIH established an experimental program for the creation and support of research facility units for clinical investigations. The grants were awarded by the Surgeon General of the Public Health Service upon recommendation of the National Advisory Health Council, and were administered by the Division of General Medical Sciences. Grants for these "Clinical and Metabolic Research Units" provided facilities for carefully controlled clinical studies. Funds could not be used for construction, but institutions could use the funds to remodel and/or renovate existing space. Primary uses of the funds were for support of vital personnel, such as research nurses and dietitians required in clinical studies. Funds were not to be used for general medical care. Support of research beds was one of the most serious needs the program addressed.

The program was designed to serve institutions with broad research programs in place and considerable clinical research potential. In its initial phases, the program sought institutions where several clinical and basic science departments could collaborate to form a clinical research unit. An individual with excellent clinical investigative training was to serve as Director of the unit under the general supervision of an Interdepartmental Committee.

The program began on a limited basis with those units funded being carefully selected by the National Advisory Health Council. In 1960, eight centers were funded at a total cost of three million dollars. The General Clinical Research Centers program became the administrative responsibility of the Division of Research Facilities and Resources (DRFR) when the latter was established by the Surgeon General, PHS, on April 13, 1962. On January 4, 1969, a notice in the Federal Register renamed DRFR as the Division of Research Resources (DRR). Currently, the General Clinical Research Centers Program supports 78 clinical research units which provide the resources and facilities for the conduct of over 4,400 clinical investigators funded by NIH and other sources. Of the 78 Centers, 75 are located within 56 of the 127 medical schools, some of which have two or more centers. The nonAIDS research budget for the Centers was $92.3 million in FY 1988 with an additional $12.5 million for AIDS research.

Since 1970 the GCRC program has supported outpatient research as well as inpatient studies. Recovery of hospitalization fees for patients receiving established medical care and therapy while participating in a research protocol, was initiated simultaneously. Ten percent of the support needed for existing Centers is met by these fees. The GCRCs provide those resources essential to the clinical studies of research investigators funded by other NIH institutes, other federal agencies, local and state governments and the private sector.

3. Human Cell and Tissue Resources

In October 1979, the National Diabetes Advisory Board sponsored the National Conference on Diabetes: Current Status and Future Directions. The conference involved approximately 200 experts in diabetes and related areas of research who were convened to assess the progress, needs, and opportunities for research related to diabetes mellitus and its complications. One important need identified during the conference involved the limited availability of human tissues and organs for use in research studies of diabetes.

In response to the identification of this need, the Juvenile Diabetes Foundation (JDF) subsequently established the National Diabetes Research Interchange (NDRI) to advance the procurement, preservation, and distribution of human tissues/organs for use in diabetes-related research. In order to support this initiative, the JDF solicited and obtained funding from the Pew Foundation in the amount of $1,300,000 for three

years (1980-1983) to develop a human tissues resource.

The provision of human cells, tissues and organs as research resources proved useful to the scientific community at large, and several NIH Bureaus, Institutes and Divisions (NIDDK, NHLBI, NEI, NIAMS and DRR) contributed to the support of these important biological materials. In the private sector, the Pew Foundation provided NDRI an additional three years of support (1983-1986) in the amount of $1,300,000.

Recognizing the importance to biomedical research investigators of a dependable source of human cells and tissues, Congress directed the NIH, through the DRR, to support the NDRI as a national human tissue/cell resource. In addition, the congress required NIH/DRR to "continually evaluate this program and present these evaluations as part of future budget presentations". In keeping with the directives of Congress, as contained in Public Law 99-500, Title III, Amendment 9, the DRR awarded a one-year, sole-source contract to the NDRI on January 8, 1987, to provide human cells and tissues for disease related research. With this action, the Federal Government became the primary source of support for this research resource. Support continued through January 8, 1989, to assure a continued source of these biological materials while NIH evaluated the research community's needs for these materials. The costs of the contract's extension were shared by DRR, NEI, NIDDK, NIAMS and NHLBI.

The Director of NIH appointed a trans-NIH committee in January 1987 to study issues associated with needs for and administration and funding of national biomaterials resources. This committee undertook as its initial task the Congressionally mandated evaluation of the research community's needs for human cells and tissues. On November 9-10, 1987, a panel of expert consultants met to advise the NIH on the needs for and uses of human cells and tissues in biological and biomedical research. The Committee determined that:

1. Human tissues and organs are essential for disease-related and general biomedical research.

2. Due to the complicated nature of processes associated with the procurement of human tissues, cells and organs, such materials are not as widely employed as their research value warrants.

   Direct support by NIH of an organization procuring and distributing these biological material resources was recommended to meet the current and future needs

-- of the biomedical research community.

C. Summary Analysis of Public Testimony:

1. Biomedical Research Support Grants.
Witnesses testified that the need for and value of this program's support far exceeds the program's funding capabilities. There was extensive testimony expressing grave concern over the possibility that the program might be discontinued.

2. Clinical Research.
Testimony focused on the lack of opportunities and support for physician-researcher career development; the imbalance in peer-reviewed support of clinical research and physician investigators as compared to basic research and Ph.D. scientists; and the fact that support for General Clinical Research Centers is not keeping up with investigator needs.

3. Human Cells and Tissues.
Witnesses stressed the increasing need for human cells and tissues in research. Particular concern was expressed over the availability of fetal tissues, as use of these tissues holds great promise for providing effective treatments of diabetes and Parkinson's disease.

II. Discussion of Principal Issues Arising in Testimony

A. Biomedical Research Support Grant Program (BRSG)

1. Public Testimony.
The volume of public testimony for the BRSG Program was large. Table 2 shows the various sources of this testimony. testimony was given by representatives of a variety of health professional schools, graduate schools, teaching hospitals and four scientific societies, including the Federation of American Societies for Experimental Biology (FASEB).

These witnesses testified that the BRSG Program was an invaluable resource, vital to the continued health of our nation's biomedical research community. The program is, in their words, extremely valuable to the research infrastructure because it provides funds literally unavailable from other sources and because it provides flexible and promptly available funds to support a variety of research needs not supported by research project grants. The BRSG Program is cost-effective and does not provide indirect costs. As one institution put it -- "after 7 years the grantee had 33 times the return on the initial BRSG investment -- an even better return than the stock market before last October". The uses of BRSG funds identified as critical to the research community are presented in Table 3.

2. Primary Issues and Concerns.

- Support for Young Investigators: Examples were given of BRSG support for the recruitment of new faculty, for assistance in establishing their laboratories and for seed money to develop highly competitive extramural grant applications. A growing number of BRSG-supported young investigators are also being awarded five-year FIRST awards.

- Pilot Studies: The BRSG Program was recognized as a prime resource for supporting novel and unexpected research findings. BRSG funds were reported to be used to support the undertaking of new ventures and the development of new emerging technologies. In FY 1986, the BRSG supported 67 small projects on AIDS and 132 projects involving mapping of human and complex genomes.

- Interim Support: Much discussion and testimony centered on the use of BRSG funds as "bridge" money to support work between grants and to fill in "gaps" in funding of established scientists.

- Central Resources: Also noted by witnesses was the fact that BRSG funds are called upon to support core facilities such as tissue culture and hybridoma facilities as well as for the upgrading of animal facilities to achieve compliance with animal welfare regulations.

- Young Physicians: Many witnesses pointed out the value of BRSG funds for the support of clinicians to engage in innovative research projects and for encouraging young physicians and dentists to pursue research careers.

- Trend of Reduced BRSG Funding: Although the witnesses considered BRSG a powerful and useful mechanism, they were aware that for the last several years, BRSG appropriations have not kept pace with the needs of their biomedical research communities. They reported that the BRSG is an important resource which is severely stressed because there has been no growth in the purchasing power of the award, and that the funds are too limited to meet the increased demand. Most institutions can fund only a fraction of internal requests for BRS funds and most expect an even larger demand in the future. One witness from a very large institution said, "the funds are minuscule -- they are obligated before we get the award."

- Instability of Funding: In FY 1987 and 1988, the BRSG was not included in the President's Budget Request, as

was the case several times in the 1970's. Congress restored the BRSG each time -- but not at a level commensurate either with the increase in research project grant funding or inflation (See Table 1). Many of the witnesses were critical of NIH for the elimination of the formula grant from the budget requests. Many testified to the disastrous effects total elimination of the program would have on their institution's research productivity.

- Maintaining the Current Threshold: Witnesses from several Health Professional Schools (Nursing and Dentistry in particular) do not want to see the eligibility threshold requirements raised beyond the current policy -- three PHS research project grants and a total of $200,000 in direct and indirect costs. [There are no current or pending BRSG policy changes under consideration at NIH].

  Small nursing and dental schools find it difficult to meet the current threshold requirement and suggest that alternative mechanisms for determining eligibility be developed to meet the needs of these smaller institutions.

  A summary of the primary concerns expressed is given in Table 4.

3. Recommendations.
   Public Witnesses recommended that the BRSG Program be retained and its funding level increased. It was recommended that NIH's administration protect the BRSG program budget. Table 5 summarizes the recommendations.

4. Option for Consideration.
   Maintain support for the BRSG without regard to the impact of mandated budgetary controls on the balance of the portfolio of NIH grant mechanisms.

B. General Clinical Research Centers

1. Overall summary analysis of public testimony.
   Concerns were expressed that more opportunities, in terms of positions, need to be available to support the research career development of junior physicians; that peer-reviewed support of clinical research and physician investigators does not fare as well as that for basic research and PhDs; and that support of the General Clinical Research Centers Program is not keeping pace with investigator needs.

   Several of the witnesses testifying in this area stated

that fewer physicians are pursuing biomedical research careers because of the perceived difficulties in obtaining peer-reviewed funding for research. The perception is that investigators with PhDs fare better than MDs through the NIH peer review system, and that funding for clinical research is difficult to obtain through that mechanism. Finally, concern was raised about the viability and funding of the General Clinical Research Centers Program in view of the perceived marked cutbacks in fiscal year 1987.

2. Essential elements of the testimony and views of public witnesses.

Opportunities for the development of clinical investigators are limited. One witness stated that the Physician Scientist Award Program is an excellent one but the number of individuals funded through that program is too few to make a significant impact. Other witnesses cited the Clinical Associate Physician Program, funded through the General Clinical Research Centers Program within the Division of Research Resources, as an excellent mechanism to fund the career development of physician investigators. Witnesses agreed that fewer physicians are electing careers in biomedical research because there are limited opportunities to obtain training and career development for the physician-scientist. Moreover, other factors intervene, including pressures on physician-faculty to assume progressively more health care delivery responsibilities. As a physician-faculty member spends more time for patient care efforts, less time is available for keeping abreast of current research. As a result, the individual's competitive edge for funding of his/her research is diminished or lost. Witnesses stated that funding for clinical research is not as readily available as that for "bench research."

It was especially noted that "Dental research has a great need for additional manpower, especially for researchers who also have the clinical background to achieve relevance of their research to oral health problems." Witnesses referring to clinical research needs of dental scientists recommended "nurturing dental research within the GCRC programs".

Several of the witnesses underscored the need for stabilized funding of the General Clinical Research Centers, which are viewed as a national resource important for the interfacing of clinical and basic research. In addition, investigator-initiated grants for clinical research that are funded through other components of the NIH may fail to provide adequately for

some components of research protocols carried out in a General Clinical Research Center. Thus, added burdens are placed on the investigator and the host GCRC site.

3. Status of NIH activities.
Figure 1 provides a summary of funding mechanisms and the number of physician/dentist investigators receiving support through those sources which include the Modified Research Career Development Award (K04), the Clinical Investigator Award (K08), the Clinical Associate Physician (CAP) Program, funded through competitive supplements to existing General Clinical Research Centers within the Division of Research Resources, the Physician Scientist Award (K11) and the Dentist Scientist Awards (K15). Between fiscal years 1982 and 1986, the number of scientists supported through those mechanisms has increased almost twofold. The number of individuals supported through the Physician Scientist Award has increased almost fourfold since the inception of that Program in 1984. On the other hand, there has been a steady decline in the number of physician scientists supported through the Modified Research Career Development Program (K04). Nonetheless, overall there is an increase in the number of physician-investigators supported through those Programs.

Among applicants competing for NIH grant support there are fewer MDs than PhDs. Figure 2 summarizes the demographics of applicants by degree for competing R01s between 1975 and 1985. Over that time span, the number of physician applicants remained relatively constant at approximately 1,000. The number of PhD applicants also remained relatively constant, at approximately 3,000, up to 1980, but increased to 3600 in 1985. Figure 3 presents a similar analysis of applicants for noncompeting grants between 1975 to 1985. Figure 4 compares award rates for MD, PhD and MD/PhD applicants.

The viability of the General Clinical Research Centers Program and the appropriateness of its funding level was raised by witnesses. The network of 78 Centers constitutes an indispensable, flexible resource for interfacing basic and clinical research and for the career development of junior physician faculty through the Clinical Associate Physician Program. Inadequate funding of individual investigator-initiated projects that are supported by other components of NIH, can lead to financial pressures on the Centers.

In fiscal year 1987, the GCRC Program's budget was 6.9 percent greater than in fiscal year 1986. However, third party offsets, which defray the cost of operating

those Centers, continued to decrease. Figure 5 summarizes the progressive decline in (Category B and C) patient days for which cost offsets are provided. That trend has been present for the past several years and will continue.

Funding of the Program over the past five years is summarized in Figure 6. AIDS-related research is expanding, reflecting the clinical and basic research emphasis in this area across the National Institutes of Health. The total 1988 budget, AIDS and nonAIDS research, is 10.8 percent greater than the 1987 GCRC Program budget. However, this increase reflects primarily the emphasis on AIDS.

The nature of GCRC research continues to change and not only emphasizes outpatient studies but also leads to proportionately more research days (Category A) and fewer days offset by third-party payers. Contemporary research on the Centers continue the trend of recent years toward increased use of outpatient visits and a concomitant decrease in inpatient days.

4. Options for consideration:

   - o Ascertain the optimum number of Physician-Investigators to be supported through the several NIH Programs that will assure adequate career opportunities for physicians in clinical research.

   - o Maximize efficient utilization of the GCRCs for NIH-funded clinical investigations by more effective coordination between the managers of the GCRC program and extramural research administrators within the NIH Institutes.

C. Human Cells and Tissues

1. Statement of the Issue or Concern.
Progress in research in diabetes and other chronic human diseases could be facilitated by increasing investigators' access to human cells and tissues. Special concern was expressed over the negative impact on research that inaccessibility of human fetal tissues produces.

2. Background.
Human cells and tissues, especially fetal tissues, are critical resources to the research community. Model systems employing human cells in culture are used in most areas of biomedical research. Ready access to reliable sources of tissues promotes

research in a broad spectrum of human diseases. Use of fetal tissues especially has led to development of promising treatments for major chronic debilitating diseases, such as diabetes and Parkinson's disease. Resources capable of providing human tissues to researchers in response to their expressed needs serve to promote progress in a wide array of research disciplines.

3. Essential Elements.
Limiting access to human cells and tissues is viewed as a direct threat to progress in iomedical research. Particular concern exists over limiting availability of fetal tissues for research. Such tissues are unique and offer opportunities for basic biomedical studies and treatment modalities which are inaccessible otherwise.

4. Views of the Public Witnesses.
Witnesses in New York and Chicago testifying for the Juvenile Diabetes Foundation and the Juvenile Diabetes Foundation International stressed the importance of human cells and tissues, particularly human fetal tissues, to research progress in diabetes and other diseases.

5. Status of NIH Activities.
NIH held a workshop on human cell/tissue resources on November 9-10, 1987, to assess the needs for these biomaterials throughout the biomedical research community.

The Workshop report -- "The need for and Management of Human Tissue for Research Purposes" -- recommends that: "NIH should continue to support and encourage human tissue research by support of organizations providing tissue to researchers. Support of networks for normal tissue procurement through the NIH Division of Research Resources and support for disease-specific tissue procurement organizations by NIH categorical institutes are both appropriate mechanisms for this encouragement."

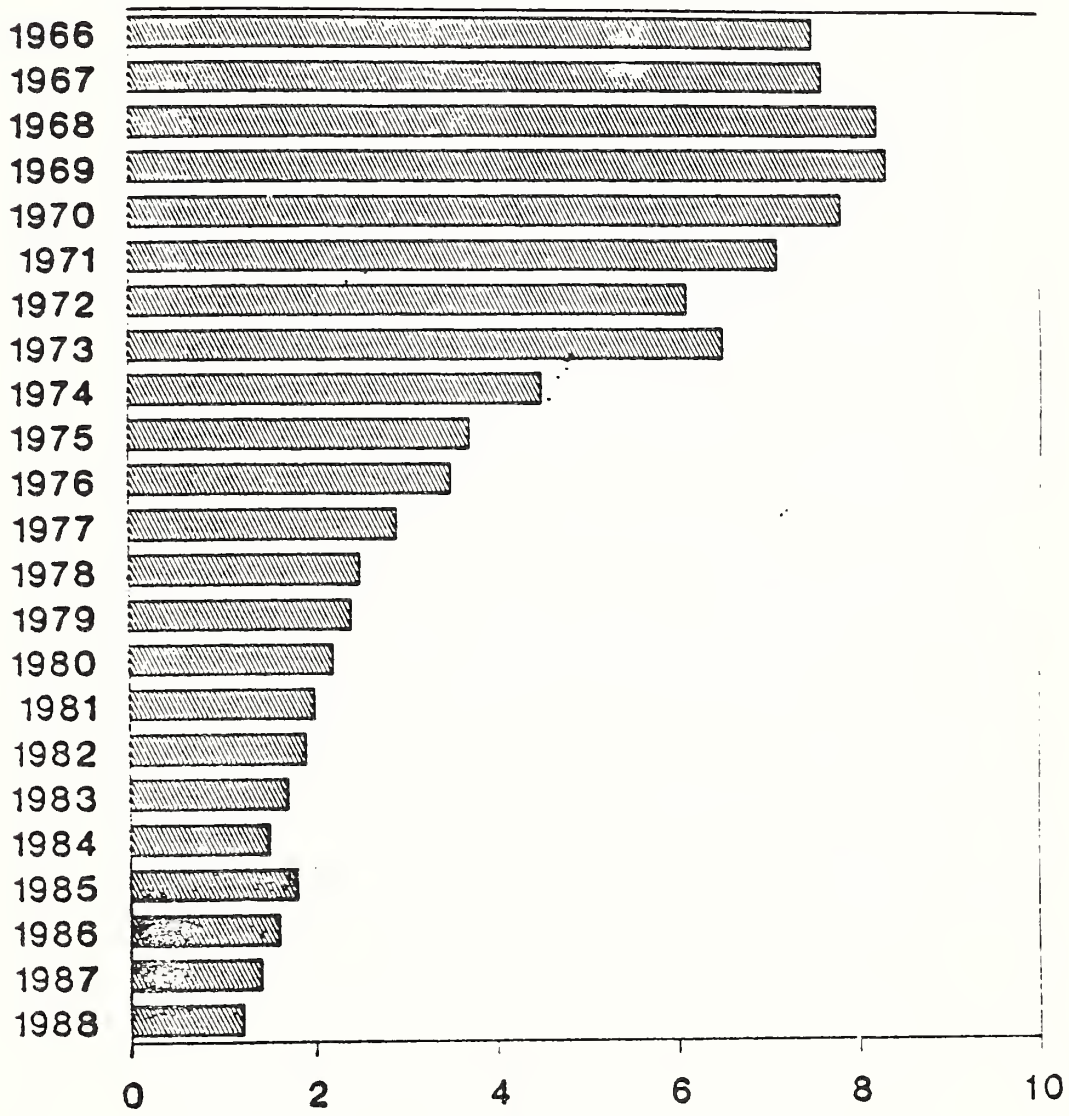
The Division of Research Resources will soon issue a competitive contract solicitation for a national human cells, tissue acquisition/distribution network. Access to such materials is now provided through a NIH-funded contract with the National Disease Research Interchange. Individual NIH institutes are also continuing to provide support for disease-specific tissue procurement resources.

Use of fetal tissue in research and the associated societal concerns with its use are currently under study by NIH. A moratorium on some NIH supported research using fetal tissues is in place pending the outcome of this study (See attachments 1 and 2).

6. Options in Addressing the Issue.
NIH is following the recommendations in the report on Human Tissue Resources.

TABLES, FIGURES AND ATTACHMENTS

BIOMEDICAL RESEARCH SUPPORT PROGRAM
Funding History



As percent of NIH grant funds available

Table 1

TABLE 2

BRSG: Sources of Public Testimony

Type of Institution	Number Providing Testimony
Graduate Schools	10
Schools of Dentistry	9
Schools of Medicine	6
Hospitals	3
Schools of Nursing	2
Associations:	4
American Physiological Society	
American Association of Dental Schools	
FASEB	
American Dental Association	
Other	3
Total	37

TABLE 3

Critical Needs Supported by BRSG Funds
(from Public Testimony)

Support for:

1) Promising New Investigators

2) Pilot Studies

3) Interim Support

4) Central Resources

5) Young Physicians

TABLE 4

BRSG: Concerns of Public Witnesses

1) Trend of Reduced BRSG Funding in Recent Years

2) Instability of Funding

3) Maintenance of Current Threshold for Eligibility

TABLE 5

BRSG: Recommendations of Public Witnesses

1) Strongly Urge that BRSG Not Be Eliminated

2) That BRSG Funding Be Given Long-Term, Sufficient and Certain Funding

3) That the NIH Administration Recognize the Value of These Funds and Protect Them in the Budget Process

NIH MAJOR CAREER DEVELOPMENT AWARDS
Individual Awards

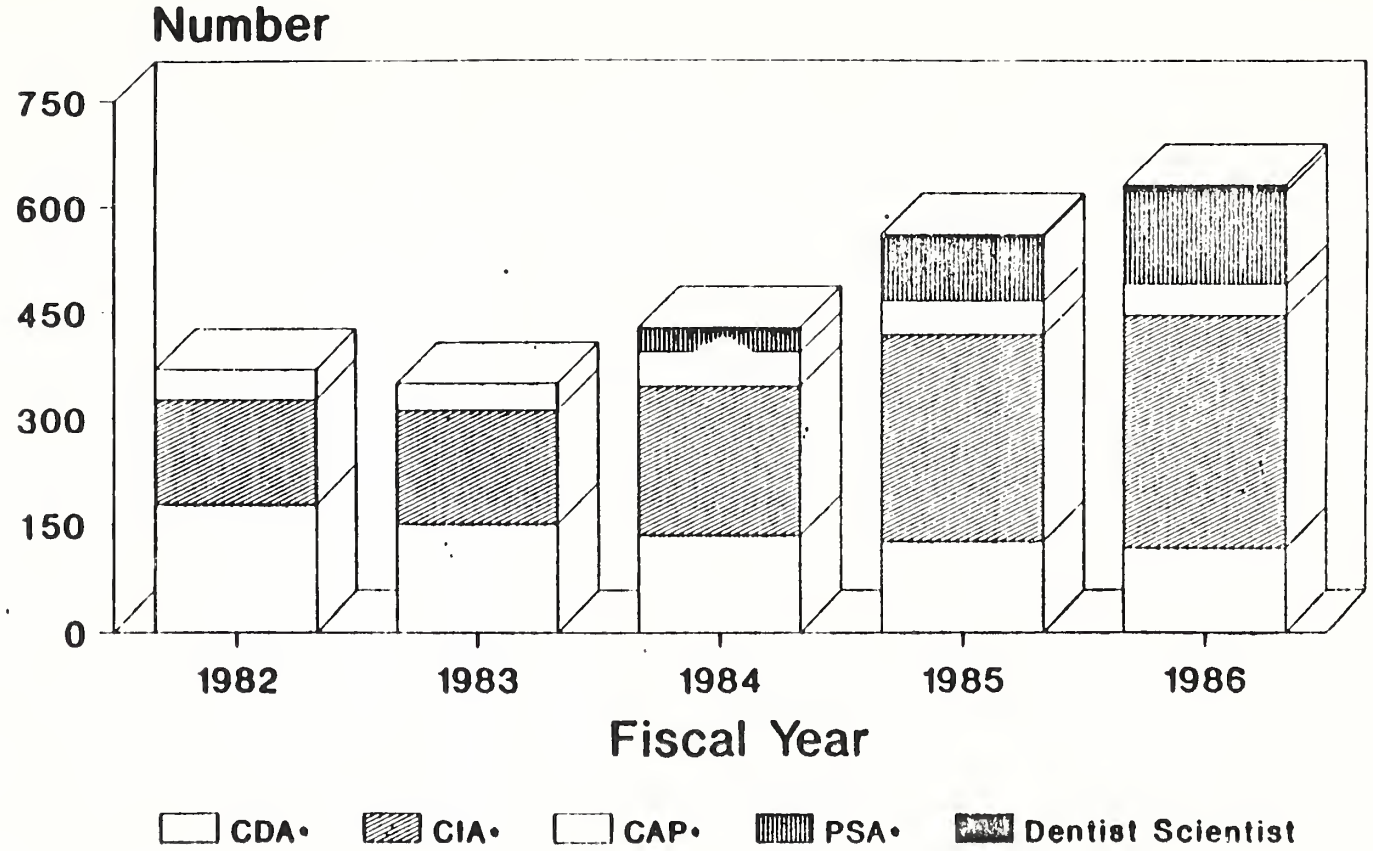


Figure 1

• MDs only

DEMOGRAPHICS OF R01 APPLICANTS BY DEGREE
Competing Grants: 1975 TO 1985

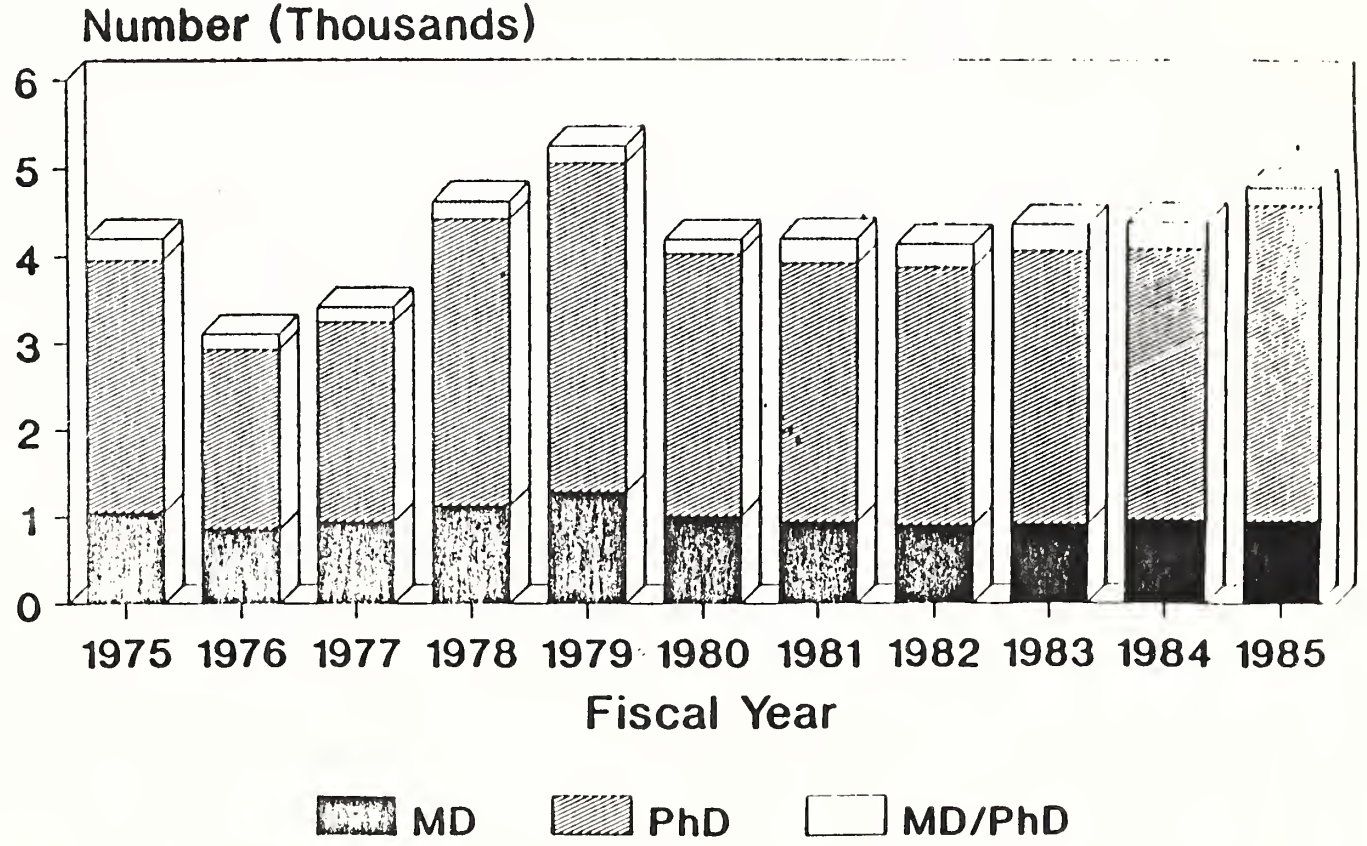


Figure 2

"Competing" includes Types 1, 2 and 9

DEMOGRAPHICS OF R01 APPLICANTS BY DEGREE NONCOMPETING GRANTS: 1975 TO 1985

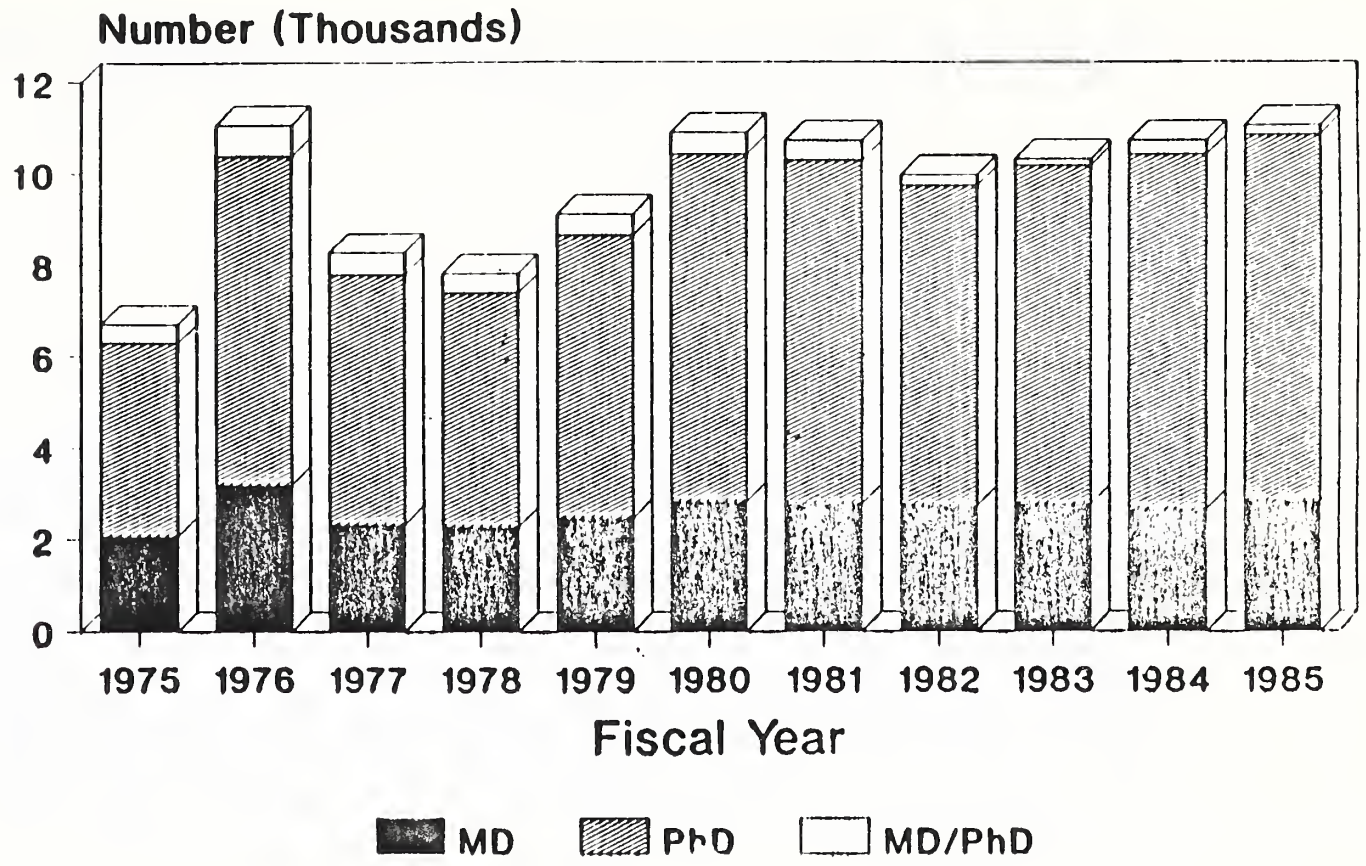
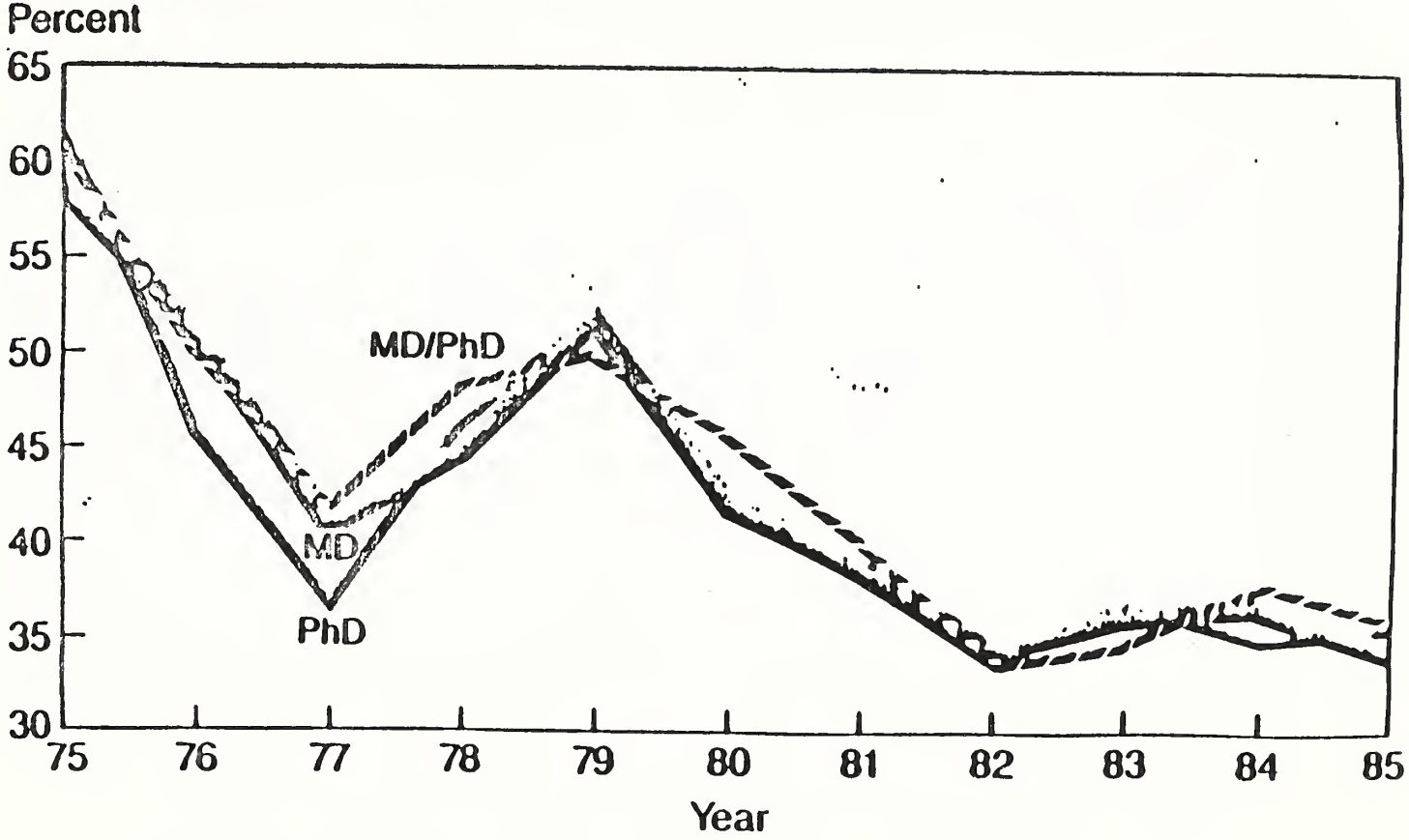


Figure 3

Award Rates of Competing R01s by Degree, 1975 to 85



"Competing" includes Types 1, 2 and 9

Figure 4

GENERAL CLINICAL RESEARCH CENTERS
DISCRETE CENTERS

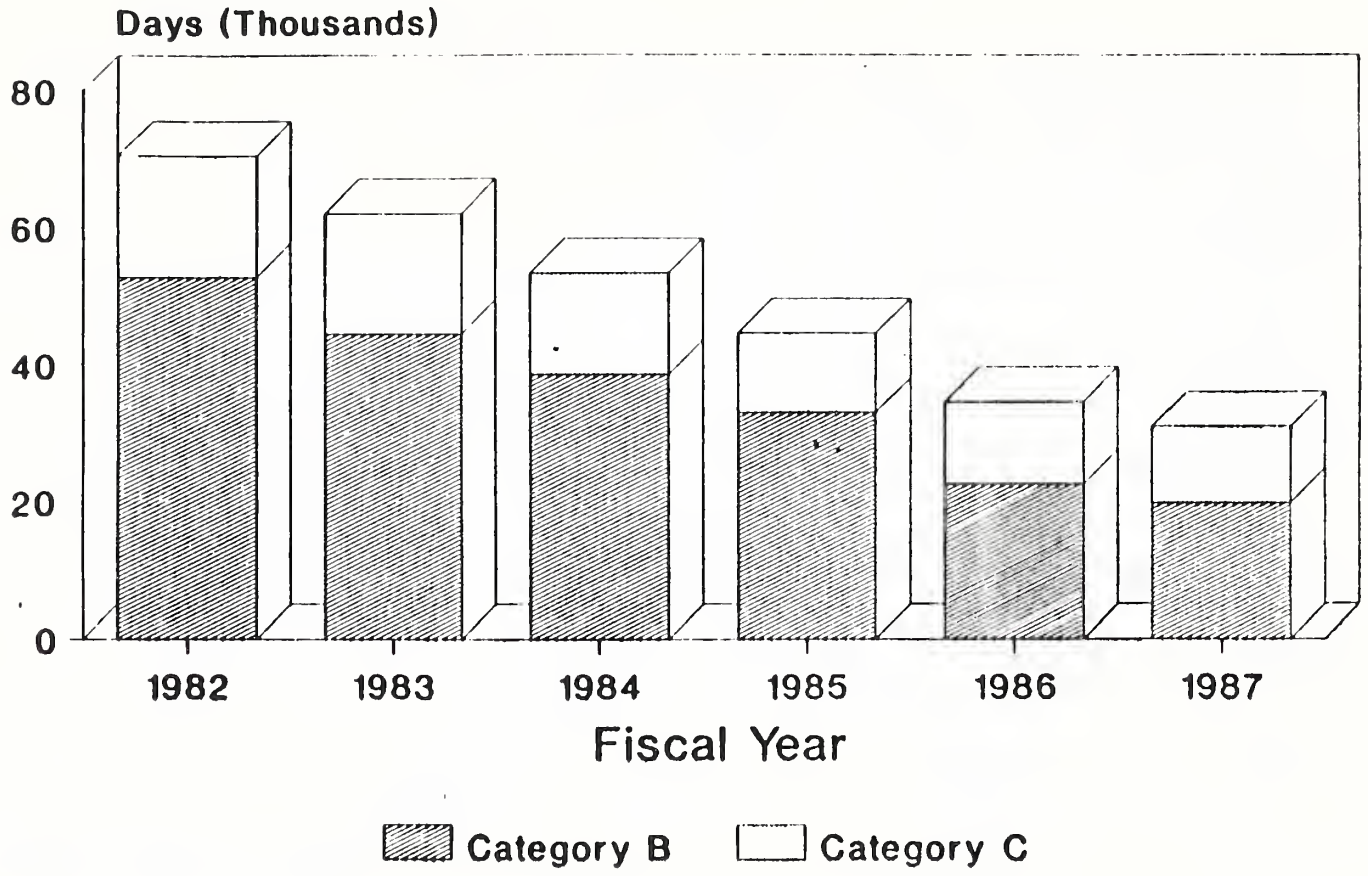
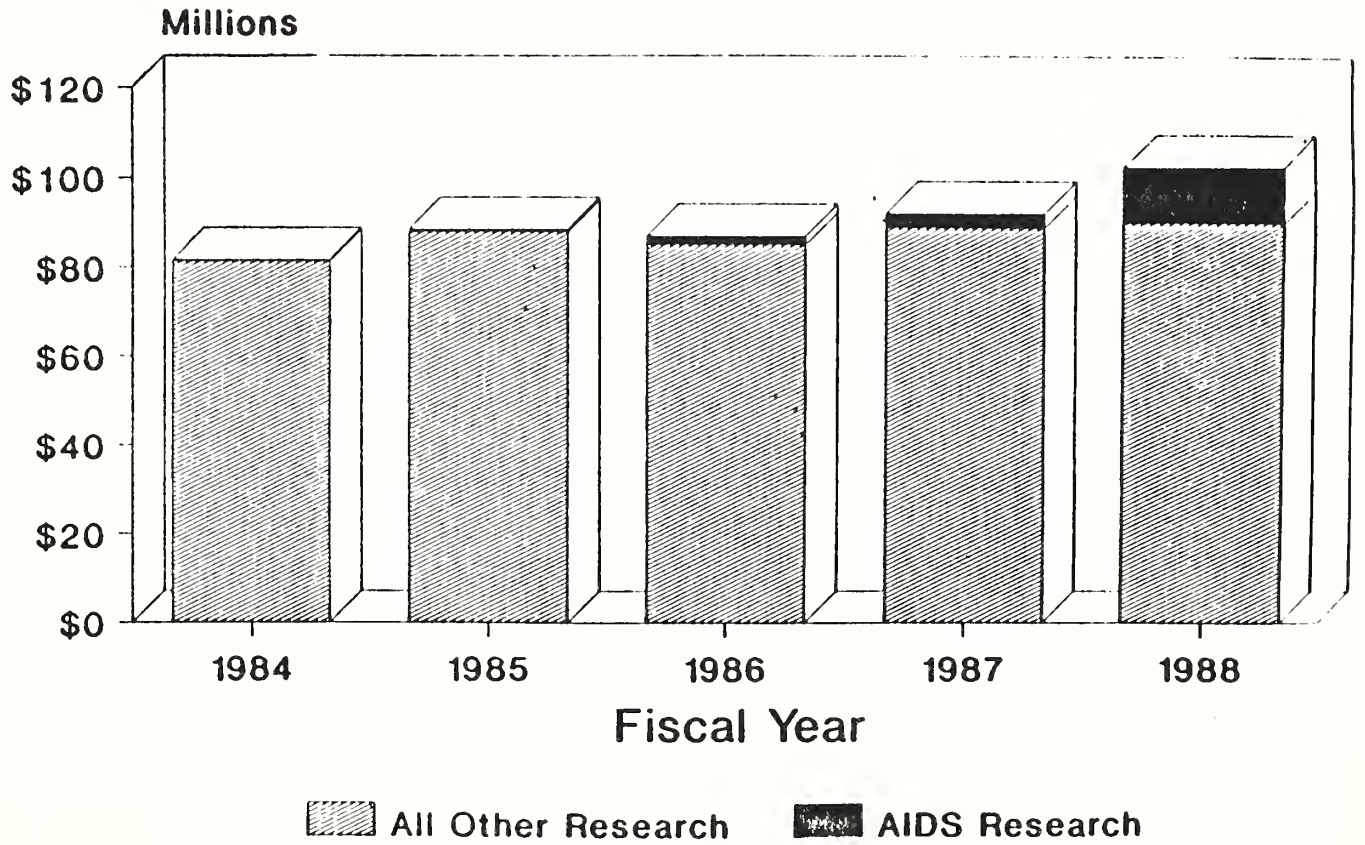


Figure 5

GENERAL CLINICAL RESEARCH CENTERS
Program Support



•separate AIDS budget FY 1988

Figure 6

Public Health Service

Memorandum

Date MAR 22 1988

From Assistant Secretary for Health

Subject Fetal Tissues in Research

To Director, National Institutes of Health

I have given careful thought to your request to perform an experiment calling for the implantation of human neural tissue from induced abortions into Parkinson's patients to ameliorate the symptoms of this disorder.

This proposal raises a number of questions--primarily ethical and legal--that have not been satisfactorily addressed, either within the Public Health Service or within society at large. Consequently, before making a decision on your proposal, I would like you to convene one or more special outside advisory committees that would examine comprehensively the use of human fetal tissue from induced abortions for transplantation and advise us on whether this kind of research should be performed, and, if so, under what circumstances.

Among other questions, I would like the advisory committee(s) to address the following:

1. Is an induced abortion of moral relevance to the decision to use human fetal tissue for research? Would the answer to this question provide any insight on whether and how this research should proceed?

2. Does the use of the fetal tissue in research encourage women to have an abortion that they might otherwise not undertake? If so, are there ways to minimize such encouragement?

3. As a legal matter, does the very process of obtaining informed consent from the pregnant woman constitute a prohibited "inducement" to terminate the pregnancy for the purposes of the research--thus precluding research of this sort, under HHS regulations?

4. Is maternal consent a sufficient condition for the use of the tissue, or should additional consent be obtained? If so, what should be the substance and who should be the source(s) of the consent, and what procedures should be implemented to obtain it?

5. Should there be and could there be a prohibition on t donation of fetal tissue between family members, or friends and acquaintances? Would a prohibition on donation between family members jeopardize the likelihood of clinical success?

6. If transplantation using fetal tissue from induced abortions becomes more common, what impact is likely occur on activities and procedures employed by aborti clinics? In particular, is the optimal or safest way perform an abortion likely to be in conflict with preservation of the fetal tissue? Is there any way t ensure that induced abortions are not intentionally delayed in order to have a second trimester fetus for research and transplantation?

7. What actual steps are involved in procuring the tissu from the source to the researcher? Are there any payments involved? What types of payments in this situation, if any, would fall inside or outside the scope of the Hyde Amendment?

8. According to HHS regulations, research on dead fetuse must be conducted in compliance with State and local laws. A few States' enacted version of the Uniform Anatomical Gift Act contains restrictions on the research applications of dead fetal tissue after an induced abortion. In those States, do these restrictions apply to therapeutic transplantation of dead fetal tissue after an induced abortion? If so, what are the consequences for NIH-funded researchers i those States?

9. For those diseases for which transplantation using fet tissue has been proposed, have enough animal studies been performed to justify proceeding to human transplants? Because induced abortions during the fir trimester are less risky to the woman, have there been enough animal studies for each of those diseases to justify the reliance on the equivalent of the second trimester human fetus?

10. What is the likelihood that transplantation using feta cell cultures will be successful? Will this obviate t need for fresh fetal tissue? In what time-frame might this occur?

Based on the findings and recommendations of the advisory committee(s), I would like you to reconsider whether you would like to proceed with this kind of research, and, if so, whether you wish to make any changes, regulatory or otherwise, in your research review and implementation procedures for both extramural and intramural programs.

Pending the outcome of the advisory committee(s)' assessment and your subsequent review, I am withholding my approval of the proposed experiment, and future experiments, in which there is performed transplantation of human tissue from induced abortions. You will note that this does not include research using fetal tissues from spontaneous abortions or stillbirths. However, I would like the special advisory committee(s) to consider whether current research procedures are adequate for the appropriate ethical, legal and scientific use of tissue from these other sources.

I believe that greater input from outside professionals and also from the public will enhance protections for research participants and will help assure greater public confidence in our work.

Robert E. Windom, M.D.

ATTACHMENT

SPECIAL NOTICE

MORATORIUM ON CERTAIN FETAL TISSUE RESEARCH

P.T. 34, 36; K.W. 0780005, 0745065, 0715190, 0755055, 1014002

Public Health Service

The Assistant Secretary for Health, Department of Health and Human Services, is instituting a moratorium, effective immediately, on research funded by the Public Health Service (PHS) utilizing human fetal tissue, obtained from induced abortions, for therapeutic transplantations. These restrictions do not apply to therapeutic research using human fetal tissue from spontaneous abortions or stillbirths, nor do they apply to nontherapeutic research uses of any legally acquired human fetal tissue. The moratorium shall remain in effect until the Public Health Service has determined what changes, regulatory or otherwise, need to be implemented in the review and conduct of PHS-funded research. No PHS funds (grant, cooperative agreement or contract) may be expended on such research during this period. Similar restrictions have been placed on research conducted by the PHS.

With a view toward establishing pertinent policies in this area, the Assistant Secretary for Health has asked the Director of NIH to convene an ad hoc advisory committee to consider the implications of human fetal tissue transplantation research and to examine the appropriate circumstances for the therapeutic use of human fetal tissue obtained from induced abortions. The NIH hopes to complete this task during the summer of 1988.

REPORT OF THE WORKING GROUP ON RESEARCH FACILITIES

Introduction

Biomedical research facilities construction in the United States has derived its resources from a combination of Federal and state appropriations, foundations, and donations by private individuals and corporations. A 1986 National Science Foundation (NSF) survey reported that the Federal Government is responsible for about 10 percent of current funding for facilities construction, but this share is expected to decline. Federal funds are used for 35 percent of the construction at private institutions versus less than 1 percent at public institutions where construction is predominantly financed by the state governments. Federal funds are provided through indirect costs, direct congressional appropriations, loans, formula grants (rarely), and occasional small grant programs. In addition, private funding has been encouraged through tax advantages.

States have a variety of mechanisms for funding, including general appropriations, bonds, earmarked taxes, tuition increases, and indirect cost recovery. However, states have varying capacities for support, and there are often competing needs within a state.

Foundations may play an important role in facilities construction. Notably successful efforts at funding by foundations rely on matching programs to attract additional support from other contributing sources. The attractiveness of charitable contributions and endowments from private sources has been diminished by recent changes in the tax law. Previously, however, private donations and endowments had provided significant support for biomedical research facilities. About 25 percent of all funds for repair, renovations, or new construction reported in the 1986 NSF survey came from private sources.

Each of these sources is expected to continue to play a major role in supporting biomedical research facilities construction in the coming years. However, it has been suggested that a significant leadership and stimulus role must be played by the Federal Government to ensure that these critical construction needs are addressed in a timely and effective manner. There is, indeed, ample precedent for such a role in the history of Federal involvement in research facilities construction, particularly that of NIH.

The NIH Construction Authority for Non-Federal Health-Related Research Facilities was initiated in 1948 with appropriations to the National Cancer Institute (NCI) for $2.3 million. Two years later, what was then the National Heart Institute (now the National Heart, Lung, and Blood Institute or NHLBI) received appropriations for about $6 million.

With passage of the Health Research Facilities Act in 1956, NIH became a significant source for support of research facilities construction. This was a unique experience for NIH in that a broad funding authority was provided for construction, renovation, and replacement of health-related research facilities. According to the Fourteenth Annual Report to Congress on the Health Facilities Research Construction Program, during fiscal years 1957 to 1969, 1,482 awards were made by the Division of Research Facilities and Resources (DRFR), NIH, to 407 institutions. Approximately $483 million in Federal funds were matched with more than $630 million in non-Federal funds. However, no funds were appropriated for these purposes after fiscal year 1968, and the NIH-wide construction authority was terminated in fiscal year 1974.

NIH has had nine separate authorities for construction, renovation, and/or replacement of health research facilities within the past four decades. Six of these authorities have been repealed or terminated. These authorities were established in most cases for relatively specific purposes (e.g., libraries, mental retardation centers, etc.), and the vast majority of construction funds have been provided through the grant mechanism. Most recently, for instance, the Congress appropriated $23.9 million in FY 1988 to the Division of Research Resources, NIH, to strengthen the research infrastructure for AIDS research by making these funds available ". . . . for repair, renovation, modernization and expansion of existing facilities, and purchase of associated equipment." While the specific construction authorities for NCI, the National Eye Institute (NEI), and NHLBI remain in effect, support in recent years has been on a much smaller scale.

Many have expressed concern that the Nation may be losing ground in maintaining the excellence of its biomedical research capability because there has not been consistent and systematic attention and support for new construction, renovation, and repair. Trends that affect the need for facilities and that substantiate this opinion include:

- The unprecedented pace of growth in scientific knowledge (e.g., in molecular and cellular biology, genetics, immunology, etc.) with concomitant expectations for continued expansion of this knowledge base including its broadened scope and complexity.

- The rapid development of scientific technologies and opportunities (e.g., magnetic resonance imaging, spectroscopy, x-ray crystallography, etc.) with attendant expanded needs for sophisticated equipment and the facilities to contain them.

- Increased requirements for construction of facilities to comply with chemohazard and biohazard regulations.

- Increased needs to support laboratory animal facility space and resources.

- The general problems of aging facilities--a backlog of repairs, replacement, and renovations.

The issues involved in addressing these trends are complex and also embedded in the context of fiscal constraints. The funding priorities that the Government and biomedical research institutions have maintained over the years are dictated by limited resources: research and research personnel have been and are of higher priority while equipment and facilities follow. The interdependence of these components is obvious. There is an inability of universities and other institutions in which biomedical research is being conducted to keep up with the demands for attracting new scientific talent without increased support to stabilize the physical component of the research infrastructure. However, as noted earlier, except for special construction authority granted for specific programs and to some of the Institutes at NIH, the Federal Government has not been a major supporter of biomedical research facilities construction for well over a decade.

Recently, the Senate Committee on Appropriations requested that the Director of the National Institutes of Health (NIH) address and report on the issue of biomedical research facilities construction. In response to that request, the Director of NIH enlisted the aid of key leaders from U.S. colleges, universities, and nonprofit research institutions to form a Study Group to:

- determine, on the basis of the existing evidence from the biomedical research community, the extent of unmet needs and concerns regarding the deterioration of biomedical research facilities and equipment

- address the roles that the Federal Government and non-Federal sources should play in such a program, including the role of indirect cost mechanisms, and

- address the mechanisms for financing the needs of the biomedical research community for upgraded facilities and equipment.

The Study Group received testimony from individuals representing a variety of organizations and institutions who provided information on various aspects related to these charges.

The testimony related to research facilities that was provided by public witnesses at the regional meetings of the Advisory Committee to the Director, NIH, covered many of the same aspects of the problem that were addressed by the NIH Study Group. For purposes of discussion, there appear to be 3 major components of the issue: (1) the order of magnitude of the unmet need for research facilities, (2) the roles and responsibilities of the various sectors in addressing the Nation's biomedical research facilities construction needs, and (3) the choice of mechanisms for financing construction of research facilities.

Assessment of Need

A wide variety of studies, employing a range of methodologies, have been carried out over the past 20 years to assess various aspects of the facilities issue. These reports and their major findings are summarized in appendix A. It may be instructive to note the results of some of the more recent of these studies.

The 1985 Survey of Cancer Research Facilities Needs, prepared for Dr. Armand Hammer, Chairman, President's Cancer Panel and the American Cancer Society, estimated that 4.7 million net square feet of new space and 1.4 million net square feet of improved space costing $2 billion are needed by 1990. The survey indicated that one-fourth of existing cancer research space needs substantial renovation.

In 1986, for instance, the NSF published a congressionally mandated study of the status of research facilities entitled Science and Engineering Research Facilities at Doctorate-Granting Institutions that was developed as a result of two quick-response surveys--one based on a short questionnaire, the other on interviews seeking "perceptions" of need.

According to the 1986 NSF survey, in the biomedical sciences, the changing nature of research requiring more sophisticated environments, not the age of facilities, appears to be a major cause of the need for facilities construction. Changing research needs generally require more sophisticated facilities. In many cases, this means converting existing facilities to accommodate the new research. Most respondents in the NSF survey said facilities needs limited the nature and scope of projects and adversely affected personnel recruitment. Limitations on facilities may also lead to conservative research approaches and a loss of experimental scientists to either theoretical science or private industry. The evidence indicated a need for expansion and renovation of research facilities, estimated at about $1.7 billion for 1985 to 1986 and $5.8 billion for the period from 1986 to 1991.

In 1986, the Office of Science and Technology Policy, Executive Office of the President, published its Report of the White House Science Council: Panel on the Health of U.S. Colleges and Universities. The panel stated that if universities are to bring their research facilities and equipment up to an acceptable level, Federal funding would be required. The panel recommended $10 billion over the next 10 years with $5 billion to come from Federal and $5 billion in matching funds from non-Federal sources.

A 1987 joint task force report of the Medical Library Association and the Association of Academic Health Science Library Directors identified a need for replacement construction in 50 percent of the Nation's health science libraries and major renovations in an additional 25 percent if these libraries are to be transformed into the information management centers required to support today's research.

Likewise, the Government/University/Industry Research Roundtable (GUIRR) report Academic Research Facilities: Financing Strategies states that

the need for construction and renovation in the next 10 to 20 years is $5 billion to $20 billion.

The recent public testimony presented at the Regional Meetings of the Advisory Committee to the Director and to the Study Group described research facilities needs across the full spectrum of the biomedical research community. Facilities needs for academic institutions, both public and private, as well as independent research institutions were discussed. Serious deficiencies were identified in physical plants and laboratory facilities in medical schools, dental schools, nonprofit independent research institutes, nursing research facilities, and research animal facilities. It was emphasized that research capabilities could be enhanced with improved facilities in podiatric medical education institutions, institutions of emerging excellence, nonprofit independent biomedical research institutes, and the academic institutions. The public statements of need for research facilities often were expanded to include consideration of the needs that are perceived to exist also for laboratory equipment and scientific instruments. The following comments of witnesses reflect the diversity of needs perceived by the scientific community.

- o One witness commented that "one of dental research's greatest needs now is improved/expanded facilities. Most dental schools have inadequate and/or outdated research facilities. NIH has not made construction funds available in a substantive way in many years and there now is a critical need to do so."

- o Several witnesses commented on specific needs that have been engendered in order for universities to comply with new standards, regulations, and guidelines for the care of animals, the use of good laboratory practice, the health and safety of laboratory workers, and the protection of the environment from hazardous substances.

    - oo As one witness noted, for instance, "in recent years we have expanded major research support facilities such as the library, animal resource facilities, hazardous waste disposal facilities, and major shared equipment facilities. We still find ourselves with a need in the next five years for up to 250,000 net square feet for biomedical and health sciences programs as well as a need for an additional 100,000 square feet for research in other disciplines, research support facilities such as expansion of the Health Sciences Library and animal resource facilities, not to mention a new chilled water plant, asbestos removal, and an improved voice and data communication system, all of which will principally support extramurally funded research efforts."

- o Another witness noted that "currently, most of the biophysical and behavioral laboratories being used by nurse scientists are 10 to 15 years old. Much of the equipment is obsolete and breakdowns are frequent. With our expanding science and with the radical

changes that are occurring in the health care arena which are necessitating different approaches to teaching and major curricular changes, our buildings are too small and our facilities are inadequate. Although the recent BRSG program for small equipment was helpful, it represented a very small drop in a very large bucket. We need replacements for large laboratory equipment, we need monies to develop state of the art laboratories including learning laboratories and we need financial help to create the space required by our expanding science."

- Yet another witness stated that "very large major research facilities may play a larger role in future advances in biological sciences than they have in the past. The NIH may need to strengthen its commitment to such infrastructure including major equipment centers which provide national resources. One example is in the synchrotron radiation area. Another may be a biophysics center to develop new techniques for biological investigations."

- Similar needs have been described pertaining to the full spectrum of the categorical research interests.

The testimony on facilities was frequently associated with references to a continuing need for new and upgraded instruments and equipment. The Shared Instrumentation Grant Program of the Division of Research Resources has been addressing these needs for 8 years. As Dr. Wyngaarden indicated at the Regional Meetings, the Program has witnessed a strong, unabated response from the biomedical community and requests for state-of-the-art instruments in the cost range of $100,000 - $400,000 to be shared among groups of PHS-funded investigators have far exceeded the available funds. For the first time in FY 1989, the Program has received 18 requests for the new laser scanning confocal microscope, illustrating the continuing impact of developing instrument technologies on biomedical research. The NIH has also responded quickly and effectively to investigator needs in the instrumentation area through the Small Instrumentation Program.

This new Small Instrument Program has made available about $16 million in both FY 1987 and FY 1988 for small equipment and resulted from an NSF/NIH study on equipment needs. The program is expected to continue at the same level in FY 1989.

In an effort to refine and improve the quantitative data that may serve as a basis for more detailed and definitive assessments of the needs for academic research facilities, the second NSF biennial survey of facilities needs, now carried out in collaboration with NIH, is being completed and the results will be available in September 1988. In the meantime, the results of existing assessments of need suggest that a long-term research facilities program may be needed to:

- Keep biomedical science at the cutting edge of the world's scientific endeavors and maintain the Nation's international preeminence in biomedical research.

- Increase the existing strengths of many research institutions by helping them achieve excellence through the addition of specific new research capabilities.

- Invest in institutions of emerging excellence that have already demonstrated a commitment to addressing the needs of the underrepresented in the health sciences to enhance and expand their research quality and productivity.

- Meet facilities needs arising from such mandated requirements as animal care, toxic waste, biohazards, and Food and Drug Administration and Occupational Safety and Health Administration regulations.

- Revitalize and renovate existing space to keep facilities current, and

- Develop and expand new biomedical research facilities based on new technology developments and the emergence of new priority research areas (e.g., AIDS).

Roles and Responsibilities

Research construction grants support not only the broad general requirements of biomedical research as described above, but also research directed at specific disease categories. Such grants provide resources for a body of research and training funded by a particular institute through grants and contracts. The provision of construction authority to NCI, NHLBI and NEI reflects congressional understanding of the connection between facilities construction and specific research objectives. Therefore, the NIH Study Group recommended that existing construction authorities in the individual institutes should be retained and utilized in support of the missions of those institutes in addition to a general NIH construction program.

- The White House Science Council Panel on the Health of U.S. Colleges and Universities in the report A Renewed Partnership, issued in February 1986, called for the Federal Government to assume greater responsibility to meet the needs of maintaining a strong science and technology base and to "bear its full share of the cost of the university research it supports." The report called for "significant increases in financial support" from the Federal Government to implement the recommendations to strengthen the principles underlying the relationships between the Federal Government and the other partners to sustain U.S. leadership in biomedical research. It further stated that:

  > "the scope of university (and college) based research is far too great to be supported through internal resources alone . . . it is the Federal contribution that will determine the rate of growth of the system . . . even more important than

the level of funding, however, is the need for stability and predictability of scope and support from Federal funding. They are essential to the effective use of financial and human resources."

- Questions are being asked about whether research institutions can respond to demands and expectations with their current capabilities or whether the high cost of research facilities exceeds these institutions' resources. Although private funding may be available, the high cost on a long-term basis may be a limiting factor. Certainly, state and local governments as well as the private sector play a role in sharing the responsibility for maintaining the Nation's physical infrastructure for biomedical research, but Federal support is considered necessary to provide stabilization to permit the most efficient continuation of our total biomedical research enterprise.

- It is generally believed that the scope of the research facilities construction problem is so great that neither the private, state, nor Federal sector can remedy the situation alone. A partnership, therefore, is considered necessary. The Government-University-Industry Research Roundtable (GUIRR), in their 1986 report Academic Research Facilities: Financing Strategies, concluded that there is no combination of universities and industries that would have a substantive effect on the problem with only token Federal Government participation.

Several public witnesses at the Regional Meetings expressed views concerning the appropriate role of the Federal Government in financing the construction of research facilities. These views are expressed in the following quotations:

- "Many universities, medical schools, and hospitals are engaged in the process of creating more appropriate research facilities through building, renovating, or leasing projects. The enormous cost of these undertakings is being incurred at the expense of direct research efforts, under serious debt expansion, or in lieu of development activities for education and clinical care. Support from the Federal Government to refurbish, replace, or build and equip anew those outdated facilities is critical for these universities, medical schools, and hospitals as they attempt to maintain this country's preeminence in fighting the vagaries of disease. Inadequate research facilities need to be addressed as a national crisis, not as an institutional dilemma."

- "Finally, the NIH must provide additional, tangible support to its university partners. Equipment must be replaced, facilities updated, and faculties and training programs expanded if the intellectual base for scientific advancement is not to be eroded."

- "The Federal Government in general, and NIH in particular, have not had substantive programs to provide for building, renovation

and re-equipping our aging physical plant for many years. State of the art research depends, in large part, on state of the art facilities. We particularly encourage NIH to provide funding, under their peer review process, to both directly provide support for facilities and instrumentation and to indirectly take away the congressional incentive for pork-barrel improvement of university research facilities."

The general tenor of testimony on this subject suggested that:

1. The Federal Government should assume a strong and well-defined leadership role in addressing the Nation's biomedical research facilities construction needs.

2. NIH should be given an overall construction authority to address unmet needs and provision should be made for a dependable and long-term flow of funds for new construction, renovation, and major repair of research facilities, and

3. Selection criteria should be based on intrinsic scientific merit, as established through the traditional NIH peer review process, with flexibility provided for special circumstances involving institutions of emerging excellence.

Financing Facilities Construction

The present methods of financing research facilities construction can be reduced to two basic mechanisms: equity financing or debt financing. Equity financing involves provision (in this case, by the Government) of up-front capital through facilities grants. Equity financing affords institutions an opportunity to move forward with construction, provides the Government an opportunity for leverage through a matching requirement, is indicative of institutional commitment, and is an alternative to the increasingly popular direct congressional appropriation. Recipients are determined by competitive merit review. Receipt of a peer reviewed grant has been shown to enable institutions to raise non-federal funds far in excess of the matching amount required. However, only institutions with a history of substantial grant support are likely to have access to the initial capital required for construction.

Equity financing of facilities construction often requires indebtedness and debt financing to achieve the non-Federal match from whatever sources of capital an institution has available, including philanthropy, tax-exempt bonds, loan guarantees, and indirect costs. However, it is problematical whether indirect costs alone can provide the needed capital for construction.

Building construction incurs ongoing obligations against the operating budget. Over the lifetime of a building, the overhead and maintenance expenses far outweigh the capital expense for construction. It is estimated that the annual operating expense for a building is 30 to 40

percent of its construction cost. It is extremely important therefore to recognize that new money must be made available to support overhead, maintenance, and amortization costs for facilities developed through a facilities construction program.

Operating costs and amortization are now recovered from indirect costs. Recent congressional and OMB concerns over indirect costs have led to occasional attempts to cap them or set them at an arbitrary percent of direct costs. Others, however, consider indirect costs to be currently underfunded, and feel that anything that increases the indirect cost burden without additional funds will decrease dollars available for research studies. Thus, it has been suggested that it may be desirable to have separate allocations of funds for capital and amortization costs in a research facilities construction program.

If indirect cost recovery is to be used to reimburse universities for the capital costs of research facilities and equipment used for federally sponsored research, then the rules for reimbursement may have to be revised to facilitate construction cost recovery. OMB Circular A21 allows for depreciation of buildings through a 2 percent use allowance, or if approved, a direct depreciation approach. However, only a small fraction of research institutions use a depreciation approach. It has been suggested that depreciation be encouraged and that the use allowance for facilities and equipment be increased. Such a change would, in effect, shorten the depreciable lifespan of research buildings and equipment.

A common approach to obtaining construction funds has been through issuance of tax-exempt bonds. The usefulness of this approach has been reduced by restrictions in the new tax law. Many institutions are at or are quickly approaching the $150 million cap on private university borrowing through tax-exempt bonds. Such institutions are inhibited from participating in a research facilities program that requires a match at the level proposed. In addition, provisions for tax incentives for donating appreciated property and for other forms of charitable giving might need to be restored. Such monies have been an important source of matching funds from the private sector in the past.

Conclusion

It is clear from the public testimony and previous reports that there is an unmet need for research facilities and related equipment, and that an expanded role for the Federal Government may be required to serve as a catalyst in meeting this need.

Legislation has been proposed to address this issue. Most recently, for instance, Senator Kennedy has introduced a bill (S.2222) to authorize the Director, NIH, "to award grants to public and nonprofit private institutions to expand, remodel, renovate, or alter existing research facilities or construct new research facilities . . . . ." At the same time, separate construction authorities in the institutes would be retained.

This report attempts to highlight for discussion the issues that must be considered in developing a program to meet the needs for construction, renovation, and repair of research facilities.

APPENDIX A

Summary of Previous Studies on Capital Needs for Biomedical Research Facilities

In 1969, NIH supported a study, Health-Related Research Facilities in the United States in the Non-Profit, Non-Federal Sector. The report presented the results of one of the most comprehensive surveys of research facilities done at that time. The survey contained information on the amount, age, and ownership of space used for health research in 1968, and it projected the amount of new space needed to overcome limitations on research by 1980. Projections of research space needs totaled 71.8 million net square feet (nsf). Space needs for new construction projects to 1980 amounted to 54.5 million nsf with an additional need of 17.3 million nsf for remodeling. Of the 54.5 million nsf projection, 36 million represented an estimated expansion of ongoing programs or implementation of new research programs.

In 1976, the American Council on Education completed the study Health Research Facilities: A Survey of Doctorate-Granting Institutions. This report, based on information provided by 155 Ph.D.-granting institutions, addressed the status of academic health research facilities, new construction in progress, and plans for R&D plant expansion in the next 5 years. Principal findings included the following:

- Of the space devoted to health research, 29 percent required renovation or replacement.
- The cost for new construction and renovation during 1985 was estimated at $547 million, with over $560 million estimated for the following 5 years.

The 1978 National Survey of Laboratory Animal Facilities and Resources prepared by the National Academy of Sciences found that half of 992 NIH grant-eligible institutions needed more space, more than one-third reported a need for renovation, and one out of six reported a need to replace animal facilities. The 1978 needs for cancer research of nonprofit biomedical research organizations for space replacement, remodeling, and additions to their animal facilities required $350 million. Another $407 million was needed to meet space needs projected from 1978 to 1988.

The 1979 National Cancer Institute's Summary and Analysis of Survey Results on Future Funding Needs for the Upgrading of Cancer Research Facilities, a survey of 106 institutions having National Cancer Institute support conducted at the request of the National Cancer Advisory Board, found 1980 construction needs for cancer research totaled $221 million. The projected needs for cancer research for 1981 to 1985 were estimated at $449 million. The types of facilities included clinical research laboratories, standard research laboratories, animal facilities, and biohazard containment laboratories.

The 1981 Nation's Deteriorating University Research Facilities Survey of 15 leading universities, prepared for the Committee on Science and Research of the Association of American Universities, found that respondents spent $400 million from 1978 to 1981 for construction, modernization, major repair, and renovation of research facilities and for special-purpose equipment. Little new construction was undertaken during this period. The estimated need for these universities was $765 million for the next 3-year period for facilities and equipment to sustain current activity levels of the existing faculty.

In 1983, an ad hoc committee of the National Academy of Science, National Academy of Engineering, and Institute of Medicine concluded in Strengthening the Government-University Partnership in Science: Report of the Relationships in Support of Science of the National Academy Complex that deterioration and obsolescence of research equipment and facilities threaten the quality and productivity of U.S. research and education. The report estimated a need ranging from $1 billion to $4 billion and called for a sustained, comprehensive program providing for facilities construction and for developing, acquiring, maintaining, and operating modern equipment.

In 1984, a survey of 25 academic institutions, Adequacy of Academic Research Facilities, estimated a need of $495 million per year for the period from 1985 to 1989 for the 25 institutions. Extrapolation to all similar universities and colleges would set a requirement of $1 billion per year.

Also in 1984, NIH completed A Pilot Study of Research Facilities Needs: Independent Hospitals and Nonprofit Institutions and Academic Institutions. In this survey of only 18 organizations, the estimated need was $440 million between 1984 and 1990, with 80 percent of the total for new construction and 20 percent for renovations.

The 1985 Survey of Cancer Research Facilities Needs, prepared for Dr. Armand Hammer and the American Cancer Society, estimated that 4.7 million nsf of new space and 1.4 million nsf of improved space costing $2 billion are needed by 1990 to accomplish stated goals. One-fourth of existing cancer research space needs substantial renovation.

In 1986, the NSF published its first congressionally mandated study of the status of research facilities. The report Science and Engineering Research Facilities at Doctorate-Granting Institutions was developed as a result of two quick-response surveys. One was based on a short questionnaire, the other on interviews seeking "perceptions" of need, covering nine fields of science and engineering at 165 doctorate-granting institutions.

The inherent limitations in this first biennial NSF survey in 1986 were clearly recognized by both NSF and NIH. Indeed, the second biennial survey, now under way, is a scientifically designed study that addresses the limitations of the first study. The results of the current NSF survey will not be available until September 1988.

According to the 1986 NSF survey, in the biomedical sciences, the changing nature of research requiring more sophisticated environments, not the age of facilities, appears to be a major cause of the need for facility construction. However, the withdrawal of both Federal and non-Federal fiscal support for construction has very likely been a critical factor in the creation of a substantial backlog of facilities construction projects.

Changing research needs generally require more sophisticated facilities. In many cases, this means converting existing facilities to accommodate the new research. Most responders in the NSF survey said facilities needs limited the nature and scope of projects and adversely affected personnel recruitment. Limitations on facilities may also lead to conservative research approaches and a loss of experimental scientists to either theoretical science or private industry. The preponderance of evidence, therefore, indicates an immense need for expansion and renovation of research facilities, estimated at about $1.7 billion for 1985 to 1986 and $5.8 billion for the period from 1986 to 1991.

In 1986, the Office of Science and Technology Policy, Executive Office of the President, published its Report of the White House Science Council: Panel on the Health of U.S. Colleges and Universities. The panel stated that if universities are to bring their research facilities and equipment up to an acceptable level, Federal funding would be required. The panel recommended $10 billion over the next 10 years with $5 billion to come from Federal and $5 billion in matching funds from non-Federal sources.

A 1987 joint task force report of the Medical Library Association and the Association of Academic Health Science Library Directors identified a need for replacement construction in 50 percent of the Nation's health science libraries and major renovations in an additional 25 percent if these libraries are to be transformed into the information management centers required to support today's research.

Likewise, the CUIRR report Academic Research Facilities: Financing Strategies states that the need for construction and renovation in the next 10 to 20 years is $5 billion to $20 billion.

June 9, 1988

ANIMAL RESEARCH ISSUES

Outline

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ANIMAL RESEARCH ISSUES

COMMENTS OF WITNESSES

The comments and concerns related to research animals expressed at the regional meetings were almost exclusively on two topics: (a) perceived harm to research caused by recent and proposed increased regulation, especially harm caused by the expense of compliance, and (b) the need for a more proactive response of the biomedical research community to the animal rights movement, especially on the part of NIH. To a great degree the two themes were interwoven, animal rights activism being seen as the primary cause of increased regulation and expense.

Impact of Regulation

Several witnesses spoke of the revised PHS Policy on Humane Care and Use of Laboratory Animals as imposing increased burdens of money and hours, while other researchers called the Policy's requirements reasonable. Most comments spoke of "regulations" generically as straining budgets and diverting time, and one witness spoke of some institutions ceasing research using animals as a result of the cost of compliance. More specific comments were:

1. The "Pet Protection Act," if enacted as law, will have a devastating effect on the cost of research with dogs.
2. A moratorium on new laws and regulations on animal care and use is needed until Government's ability to support the costs is assessed.
3. Split responsibility between USDA and NIH causes conflicts between USDA and NIH requirements.
4. Investigators must meet expensive new requirements in the middle of grant cycles.
5. Compliance with some regulations proposed by USDA, such as daily census of all animals, is physically and fiscally impossible. (Note: A daily census is not among current USDA proposals.)
6. NIH should establish a national "ombudsman" to deal with perceived or actual differential enforcement of animal care regulations in different regions.
7. NIH should take the lead in reviewing the rationale of excluding enterprises such as humane societies from provisions of the Animal Welfare Act.
8. NIH should consider alternative methods of institutional protocol review that would reduce the work load: for example, full review of only those protocols that have received a priority score making them possibly fundable.

Biomedical Research Community Response to Animal Rights Activism

A typical comment was that "Animal rights activism is one of the major threats to biomedical research in this country." The threat is seen as mediated both by laws prohibiting the use of certain animals and by enactments that can make animal research prohibitively expensive.

Several participants stressed that the entire biomedical research community must be involved in counteracting animal rights activism by

educating the public, including their own student bodies, but the major emphasis was on the need for NIH to take the lead in this endeavor.

Some of the specific points made:

1. Our own apathy is our greatest enemy.
2. We must keep our own house in order.
3. Our stand should be: we have the guidelines and regulations in place to eliminate abuse.
4. A report written by scientists who use animals is needed.
5. We must get our message across better to Congress.
6. Our Animal Care and Use Committee lay members should be people who are concerned about animals but not basically opposed to use of animals in research.

In addition to the many scientists speaking in support of the use of animals in research, two representatives of the Juvenile Diabetes Foundation expressed opposition to efforts to limit the availability of animals for research. One witness, a psychiatrist, represented an animal rights point of view. After speaking on the importance of non-animal research methods and of behavioral research into the practicalities of disease prevention, he expressed his opinion that NIH is doing badly on animal welfare issues.

BACKGROUND

Outright antivivisectionism, legitimate concern for the welfare of animals used in research, and voluntary and mandatory guidelines for institutions using laboratory animals all have long histories. All three accelerated exponentially during the 1980s. Some milestones among these rapid developments are the following:

- The IBR (Taub) Case and PETA

In 1981, the recently established People for the Ethical Treatment of Animals (PETA) brought about a police raid on the Institute for Behavioral Research (IBR) primate research laboratories in Silver Spring, Maryland, and seizure of deafferentated and normal control monkeys held there. Animal rights activists moved and hid the IBR monkeys (placed by local authorities in the custody of PETA members) to prevent their possible return to IBR. After negotiated return of the animals to local authorities, NIH agreed to the authorities' request to assume care of them. NIH suspended IBR's grant for failure to supply veterinary care. IBR employee Dr. Edward Taub was subsequently convicted of cruelty to animals, but the state court verdict was later reversed for lack of jurisdiction.

PETA leaders pursued permanent custody of the animals in the courts. In April 1987 the Supreme Court, by refusing to consider the case, let stand a Federal Appeals Court decision that the plaintiffs had no standing to sue. The Appeals Court opinion stated that permitting the case to proceed might unleash a spate of private lawsuits that would impede advances made by medical science in the alleviation of human suffering.

Along with its current projects such as attacking the National Chimpanzee Breeding and Research Program, PETA continues its publicity focus on the surviving "Silver Spring" monkeys: the deafferentated currently housed at the Delta Regional Primate Research Center and the normal animals at the San Diego Zoo. As part of the continuing effort of the DHHS to ensure proper care for these animals, the NIH recently convened a group of experts to advise on a future course of action. They met at the Delta Regional Primate Research Center, with first-hand observation of the animals and relevant clinical records. The principal recommendations range from euthanasia in the near future for certain of the experimentally disabled animals to a circumscribed resocialization trial for others. NIH intends to carry out the actions indicated above, working closely with the Delta Center and the owner of the animals: the Institutes for Behavioral Resources, Inc., of Washington, D.C. Copies of the report, entitled "Assessment of Recommendations for the Silver Spring Monkeys" were sent to interested Members of Congress in May 1988.

Throughout this case, PETA showed meticulous planning, obtained maximum publicity, and turned quickly to Congress--a pattern subsequently followed when acting as spokespersons for the Animal Liberation Front (ALF) and other groups that break into animal facilities and remove animals. Since 1981 PETA has grown to a reported membership of 250,000 people and an annual budget well over $3 million. It is one of the largest among a complex array of animal rights organizations.

- Activists' Strategy

Most Americans recognize some need for research using animals and are also opposed to cruelty to animals. Antivivisectionists reiterate constantly that biomedical and behavioral research using animals is pointless or duplicative, but they use ostensible "horrible examples" to make an impact. They seek to identify research projects and animal facilities that have questionable features or in some other way are possible candidates for negative publicity and letters of protest to Congress. With public reaction primarily in mind, they have focused especially on dogs and primates. Some of their targets have later been found in violation of the NIH Guide for the Care and Use of Laboratory Animals (NIH Guide) and PHS Policy; most have not. Whether or not a break-in and "liberation" of particular animals is involved, the goal is to discredit the entire animal research community and our system for ensuring humane care and use, in order to make drastic restrictions more palatable to legislators and public. This has been clear in the many well-publicized cases of the 1980s such as the University of Pennsylvania Head Trauma Laboratory. Some organizers of campaigns for legislation prohibiting release of pound or shelter animals to research facilities have stated that such "pet protection" agitation is ultimately intended to reduce the number of research projects involving dogs rather than merely to change the source. In a more recent development, animal rights groups in California have joined with activists concerned about genetic engineering in opposing construction of new animal facilities at Stanford.

- U.S. Government Principles Published 1985

The Office of Science and Technology Policy published the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training in the Federal Register, May 20, 1985. The principles, prepared by the Interagency Research Animal Committee, underpin the revised NIH Guide and the revised PHS Policy on Humane Care and Use of Laboratory Animals.

- NIH Guide Revised 1985

The sixth revision of the Guide for the Care and Use of Laboratory Animals was prepared by the Institute of Laboratory Animal Resources and issued by NIH in 1985.

- Revised PHS Policy

A series of random site visits to NIH awardee institutions during 1983-84 showed that the reviewed institutions all shared concern for proper care and use of animals and that institutional assurances remained a sufficient basis for assessing compliance with PHS policy and the NIH Guide. However, a number of institutional shortcomings were identified, and NIH determined that the assurance system must be strengthened and site visits continued. In addition to increased emphasis on institutional accountability, the 1985 revision of the PHS Policy on Humane Care and Use of Laboratory Animals greatly expanded the role and authority of the Institutional Animal Care and Use Committee (IACUC) and required significantly greater specificity in the institution's Assurance Statement. In the 1985 NIH Reauthorization Act, Congress mandated and slightly modified the same requirements and applied them to all PHS intramural programs; a revised PHS Policy, now with statutory authority, was subsequently issued in 1986.

- "For Cause" Site Visits

Several "for cause" NIH site visits to awardee institutions during 1985-86 identified serious program deficiencies which resulted in sanctions. The number of such site visits decreased significantly in 1987-88, largely because institutions are aware that self-assessment and prompt reporting of alleged or perceived deficiencies are important.

- 1985 NIH Reauthorization Act

In addition to modifying the PHS Policy and making it statutory, this Act required training in humane animal use for scientists and other involved staff and NIH funding of activities to develop alternatives to animal research. The Division of Research Resources (DRR) has been the NIH focal point for development of alternatives to use of animals, including measures that reduce the numbers of vertebrates used, produce less pain or distress, validate or demonstrate the reliability of non-animal methods, or further develop non-vertebrate animal research methods that have been found valid and reliable.

- 1985 Amendments to the Animal Welfare Act

Among other changes, amendments to Part 3 of the Act required the USDA to enact regulations establishing standards for the exercise of dogs and promoting the psychological well-being of nonhuman primates. Parts 1-2 of the regulations were published as proposals in the March 31, 1987, Federal Register. PHS comments on the published proposals were coordinated through the NIH's Office for Protection from Research Risks (OPRR) and submitted to USDA on behalf of the PHS by Dr. Wyngaarden.

CURRENT NIH ACTIVITIES INVOLVING ANIMALS IN RESEARCH

NIH is engaged in a number of activities directly responsive to the principal issues raised by witnesses at the Regional meetings.

Policy and Regulation

- 1985 Amendments to the Animal Welfare Act

The 1985 amendments required consultation between USDA and HHS on the development of USDA's implementing regulations. OPRR was designated the HHS office responsible for fulfilling this provision. Several NIH ad hoc committees have reviewed pre-publication drafts of Parts 1-3 of proposed regulations, and representatives of OPRR have met with USDA on several occasions to discuss committee recommendations. The USDA has been encouraged on these occasions to modify discretionary areas of proposed regulations which were not congruent with the PHS Policy. These NIH efforts have met with limited success, and the consultative process is continuing.

Since NIH commented to the USDA on the March 31, 1987, proposed regulations, Parts 1 and 2 have been revised by the USDA, with planned resubmission to OMB for Federal Register publication as either final rules or reproposals. Having received more than 8000 comments, USDA sought and obtained assistance from the NIH in reviewing comments and redrafting Parts 1 and 2. Revisions to these parts are anticipated to bring them into congruency with similar provisions of the PHS Policy. The USDA is continuing to develop Part 3 of their regulations to implement provisions of the 1985 amendments requiring the establishment of "standards." A preliminary analysis by USDA economists has determined that the rules (Parts 1-3) will have a major financial impact on organizations covered by the Act. Particularly costly are provisions governing the exercise of dogs and promotion of the psychological well-being of nonhuman primates. Given the scope of the projected costs, a more thorough review within the Executive Branch and the OMB may be necessary, with several possible outcomes. USDA might be directed to revise the most costly provisions of proposed regulations or Congress might be asked to reconsider the Act and address the issues of how to finance it. It seems unlikely that final rules will be implemented this year.

Part 3 has been reviewed on several occasions by an ad hoc committee of NIH veterinarians and other scientists. The committee's recommendations

have been submitted to the Interagency Research Animal Committee (IRAC) for review and will be forwarded to the Secretary of USDA by the Secretary of HHS. In a very recent development, the OMB has determined that an assessment of the economic impact of the proposed regulations on Federal research institutions is necessary, and has asked the IRAC to collect the necessary cost data from its representative agencies. OMB has also requested the IRAC agencies' review and comments on the proposed regulations before further Federal Register publication of Parts 1, 2 or 3.

- Implementation of PHS Policy

Since the period when the 1985 revisions of the PHS Policy on Humane Care and Use of Laboratory Animals were being made, OPRR has continued to conduct regional workshops on its implementation for the scientists, administrators, IACUC members, and others involved. The most recent such workshops were held in March 1988 in Durham, North Carolina, May 1988 in Albany, New York, and this month in Kansas City, Missouri.

OPRR also met with an ad hoc Advisory Committee on PHS Policy Compliance Evaluations in October 1987 to review its procedures in investigations of laboratory animal care and use programs at awardee institutions. The committee was made up of senior administrative officials from institutions that had been investigated or otherwise subject to OPRR compliance oversight activities. The results of this meeting, to be published as "The Claremont Report," are expected to assist institutions in compliance and to improve OPRR's procedures in future activities of this kind.

- NIH Initiatives to Reduce Use of Vertebrates in Research

Continuing its responsiveness to requirements of the 1985 NIH Reauthorization Act, the Biomedical Models and Materials Resources Section (BMMRS), DRR, recently held a conference on marine life resources at the Duke Marine Laboratory, Beaufort, South Carolina, to assist with planning for future support of marine animal resources. NIH has also recently reissued an updated Program Announcement seeking further grant applications on research into methods that replace or reduce vertebrate animals used in research, or lessen their pain and distress.

The Biomedical Engineering and Instrumentation Branch, DRS, held a symposium in Boston, November 1987, on Technological Advances in Models for Biomedical Research, and an NIH Technology Assessment Workshop on this subject, including mathematical, physical, and in vitro models, is planned for fall of 1988.

- National Academy of Sciences Evaluation Study of the Use of Animals in Research

Estimating the numbers of animals used in research in the United States presents great methodological problems, and current estimates differ very widely. NIH contracted with the National Academy of Sciences for a study including a national survey of facilities, both public and

private, using laboratory animals (conducted by the Institute of Laboratory Animal Resources), and a study of the issues associated with the uses of animals in biomedical and behavioral research (conducted by the Commission on Life Sciences and the Institute of Medicine). A draft survey instrument has been prepared and a pilot survey conducted. The definition of the survey universe and the sampling strategy are being completed. The discussion of issues is expected to be delivered in June 1988.

- Intramural Office of Animal Care and Use

In response to the revised PHS Policy on Humane Care and Use of Laboratory Animals, NIH has established an Office of Animal Care and Use to ensure that intramural programs are in compliance with all policies and rules on animal care and use. It is part of the Office of the Deputy Director for Intramural Research.

Extramural Animal Resource Improvements

The Division of Research Resources has been allocated additional funds in the last three years to improve the facilities in animal resources. In 1988 almost $12 million has been awarded for this purpose to 40 institutions. These funds allow only equipment purchases and alteration and renovation of existing buildings; matching funds are required for the building improvements. Estimated needs throughout the country are much larger than can be addressed with resources currently being provided without construction authority. DRR has also awarded limited funding for research to identify optimal housing and husbandry procedures for research animals. These efforts could be supported more extensively. Finally, the number of veterinarians being trained in laboratory animal medicine and research has been increased by more than 70 percent in the past two years.

NIH Outreach on Importance of Research Using Animals

- Biomedical Research Coalition Formation

NIH representatives have begun to work with other organizations concerned with biomedical research issues, including the Association of American Medical Colleges, to build a coalition of organizations and groups interested in the appropriate use of laboratory animals for research, product safety testing, education, and agricultural purposes. The coalition includes more than 60 voluntary national health associations, representing millions of people, that are signatories to a statement in support of continuing animal research. One of the first collaborative actions will be a jointly-sponsored educational event to be held at NIH.

- Congressional Briefings

On February 19, 1988, the Division of Research Resources organized a briefing for Members of Congress and key staffers on "The Use of

Chimpanzees in AIDS Research." The National Chimpanzee Breeding and Research Program is a current target of attack for PETA and others.

Working with its "Partners in Research" -- academia and industry -- NIH is conducting a series of Congressional briefings on the use of animals in research. The first session, held June 17, 1988, was on "Why Animals are Essential in Biomedical Research." Tentative titles for sessions planned for September and October are "How Animals Used in Research are Protected" and "Animals in AIDS Research."

- Animal Legislation Activities

Random Source Animals. In a meeting with the National Association for Biomedical Research, Representative Robert Mrazek, chief sponsor of H.R. 778, stated that his concern is pet protection, not interference with biomedical research. The bill would prohibit the receipt of Federal funds by anyone who acquires, or uses for research, animals obtained from animal shelters. His staff is reportedly working on a "compromise" measure which, it is hoped, will address the concerns of the biomedical research community. Dr. Raub has met with Representative Robert Mrazek to discuss pet protection; Mr. Mrazek reiterated his willingness to work toward compromise legislation.

Senator Wendell Ford, who introduced the Senate version of Mr. Mrazek's bill (S. 1457) in June 1987, recently introduced S. 2353, the "Pet Theft Act." It would prohibit class B animal dealers from obtaining any live random source dog or cat from any source other than a State, county, or city owned and operated pound or shelter, or from an individual who has not bred and raised such dog or cat on his own premises. In introducing S. 2353, Senator Ford stated that S. 1457 "became too embroiled in the highly controversial matter of pound seizure. Today I separate the two issues, leaving pound seizure for some other person to deal with on some other day."

NIH is sending a "Dear Colleague" letter to Members of Congress explaining the NIH policy on use of random source animals. Two members of the House of Representatives have recently written to constituents mistakenly stating that NIH uses only purpose-bred animals in the intramural programs.

LD-50 Test. H.R. 1635 would prohibit Federal department or agency heads from considering LD-50 test results when determining product safety, labeling, or transportation requirements for the purpose of Federal regulation, and would require that all department and agency heads promulgate regulations which specify that nonanimal toxicity tests be used unless it is determined that in certain limited cases the animal toxicity test is more valid. The bill was introduced in March 1987 by Representative Barbara Boxer. At NIH's request, Dr. David Rall, Director, NIEHS, testified in opposition to the bill at a hearing on May 16, 1988, stating that it would profoundly and adversely affect the conduct of biomedical research and the protection of public health.

CONCLUSION

Most of the comments on regulation at the regional meetings focused on USDA regulations, especially proposals still pending. Much NIH effort is being devoted to obtaining consistency of USDA regulations and PHS policy and to ensuring full consideration of the impact of possible expenses. As regards the comment on humane society facilities: any humane society facility that sells animals for any purpose is subject to the Animal Welfare Act.

Several witnesses viewed provisions of the PHS Policy as onerous and excessively expensive, and requested relief. However, the provisions with greatest impact on institutions, requiring IACUC responsibilities of proposal review and program/facility self-evaluation, are the heart of the assurance system and were encouraged by the NIH Guide and PHS Policy for many years before becoming mandatory. Feedback to NIH from awardee institutions does not give the impression that the provisions are widely viewed as excessively onerous or expensive, and suggestions for improvement of the system are sought and welcomed. One witness suggested full IACUC review only of the projects from their institutions that have received a priority score. We believe that this procedure could put an intolerable pressure on the committees to approve.

NIH is in complete agreement with the two basic themes expressed by many witnesses at the regional meetings: regulation without sufficient consideration of resultant expense is a threat to the performance of vital biomedical research, and the biomedical research community must actively and energetically provide information to the public and to the Congress on the essentiality of research using animals and the strength of the system for ensuring humane treatment of the animals used in that research. NIH indeed has a responsibility to play a leadership role in these efforts. As summarized here, much has been done and is being done, and more coordinated efforts are developing. We are especially heartened by the increased participation of national voluntary organizations representing victims of particular diseases. Greater participation by the beneficiaries of biomedical research must be matched by greater participation of individual scientists who use animals in their research. Furthermore, NIH, in meeting its leadership responsibility on animal use issues, can function only in ways appropriate for an agency of the Federal Government, especially as regards its use of funds and its relations with Members of Congress.

We would stress especially that the biomedical research community must keep its house in order. Regulation is not merely a result of activism by antivivisectionists. Our commitment to humane care and use of animals must be as real as our commitment to the advancement of knowledge.

Report on Flexibility and Continuity of Research Funding

June 1988

FLEXIBILITY AND CONTINUITY OF RESEARCH FUNDING

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REPORT ON FLEXIBILITY AND CONTINUITY OF RESEARCH FUNDING

I. INTRODUCTION

A. General Overview

Flexibility and continuity of research funding are topics of widespread interest and discussion in today's research environment. NIH is committed to create as stable an atmosphere as possible for research. Policies and practices have evolved over the years to adapt to changing fiscal situations and to maintain a strong national research enterprise. As Dr. Wyngaarden commented during the June 1987 meeting of the Advisory Committee to the Director, "As long as there is at least a small amount of growth in the system, you can maintain reasonable stability, but without that it's very tough." Several administrative practices such as interim funding and orderly termination support, carryover of unobligated funds, alternative funding strategies, and long-term support of research have been developed during the history of NIH in order to provide stability to the research investigator and the research environment.

B. History of Issues

Interim support is partial support offered to a grantee institution when necessary to prevent a hiatus in funding pending a final determination of the award of a competing renewal application. This mechanism has been used to prevent an ongoing research project from lapsing when a deferred competing continuation application is undergoing further peer and Council review, and when a funding decision is pending for a favorably reviewed application with a priority score that does not reach the payline but later funding is anticipated. Until about 1970, funding resources were sufficient to support about 90 percent of approved applications and also to provide interim support when necessary. But, as funds became more limited, interim supplements were awarded less often and in smaller amounts. Today, interim funding is rarely offered and then only in a few hardship cases.

When interim support was awarded but the relevant NIH Institute was not able to fund the competing renewal, the interim supplement was often considered to be orderly termination support. Termination support also was provided when a renewal application did not compete successfully and it was too late to bring the research to an orderly close. To avoid this situation, investigators with larger program project grants were encouraged to submit competing renewal applications up to two years in advance of the end of the competitive segment so that, if the renewal application competed unsuccessfully, time would be sufficient to submit an amended application, or to bring the research program to an orderly completion. Today, orderly termination support is offered only in cases involving unusual hardship.

Carryover support refers to authorized transfer of an unobligated balance to a subsequent budget period for utilization. Carryover currently is authorized only in special circumstances, but prior to the mid-1960s (before development of the project period concept) carryover was automatic and an investigator could carry over an unobligated balance up to $5,000 per year to meet

unanticipated needs. Between the late 1960s and early 1980s, carryover was authorized only for specific individual items and needs. In 1986, the Florida Demonstration Project (FDP) was initiated to assess the impact of simplifying post-award administration of grants. In this, and in such recent NIH programs as the Method to Extend Research in Time (MERIT) and First Independent Research and Transition (FIRST) awards, automatic carryover has been used as an important mechanism for fostering research stability. The FDP has led to a pilot project to examine the impact of such authorities as automatic carryover when they are delegated to grantee institutions. It is anticipated that use of these authorities will be extended in the near future.

Use of different funding strategies, such as full funding (level recommended by the study section) and cutbacks (reduced levels), have depended upon the fiscal situation at NIH. An alternative strategy, (not proposed by NIH) is the use of a sliding scale under which funds are distributed in a graduated manner on the basis of priority scores. This alternative was suggested in the late 1970s and early 1980s, when the growth of fiscal resources for research began to slow and the research community expressed concern whether funds would be sufficient to support an appropriate percentage of the approved grants. It was one of several measures suggested for temporary implementation to support a greater number of research grants.

Long-term support, i.e. increasing the length of competing segments, is an important contribution to stability in the research community. NIH grants were originally awarded for seven years but, from 1955 to 1968, awards were limited to five years. As a result of the Fountain Committee study in the 1960s with its emphasis on accountability, grants were awarded for even shorter durations, commonly three years. The burden this placed on research investigator and institution became increasingly evident during the 1970s, and, in the early 1980s, NIH encouraged study sections, Advisory Councils, and Institutes to consider increasing the duration of awards. As a result, the average duration of R01s in 1987 was 3.8 years, an increase from 3.15 years in the late 1970s. On the basis of an estimated 20,000 NIH grants awarded in FY 1987, this represents an increase of 14,000 grant years in 1987 alone, and a concomitant decrease in the administrative burden. NIH also implemented two new special programs in the mid-1980s--the MERIT award and the FIRST award--to increase the length of grant awards even further. These new programs, as well as the ongoing NCI's Outstanding Investigator Grants (OIG) and NINCDS Javits' Awards, are expected to contribute to this important component of stability.

C. Summary Analysis of Public Testimony

The practices described above were aspects of the flexibility and continuity of research funding most often mentioned by public witnesses who attended the regional meetings of the Advisory Committee to the Director, NIH, on the subject of "The Health of Biomedical Research Institutions." They recognized the contributions of NIH staff in providing excellent assistance in minimizing adverse effects of fluctuations in support. However, several witnesses voiced concern that year-to-year budget cuts and low probability of support for renewals are increasing instability in the research enterprise. They commented that new approaches are needed to enhance stability and encourage the commitment of young investigators to research careers.

Several speakers identified the need for mechanisms to support investigators who submit a revised competitive renewal, because additional costs are involved when a research project must restart after a hiatus in funding for several months. Earlier submission of renewal applications, submission of substantive supplemental information, and expedited review for unsuccessful applications were suggested in order to alleviate this problem. Interim funding of 1-2 years also would permit the unfunded applicants for renewals to demonstrate feasibility and productivity and, thus, become more competitive. A suggested approach to minimize discontinuity for unfunded competing renewals that are near the payline, was to provide routine interim support through an additional review cycle.

Investigators often maintain at least two grants to buffer the effect of an unfunded renewal. Therefore, some speakers suggested providing partial funding of 1-2 years for orderly termination of an unfunded competing renewal application, if the grant had received at least one competing renewal award.

It was indicated that automatic carryover of funds, such as that in the OIG and the MERIT awards, would result in more productive use of an investigator's funding and enhance the overall scientific effort by reducing the administrative burden.

Instead of the NIH "all or nothing" policy, under which grants are supported on the basis of the priority score, it was suggested that use of a sliding scale would increase the amount of high-quality research that could be funded and enable more investigators to continue at some level of funding. It was stated that current award rates are not sufficient to maintain the current number of scientists, much less provide for new ones, and that, because current NIH reductions are really a form of sliding scale, they should be organized on a more rational basis.

Some public witnesses stated that long-term, adequate, and assured funding, without budget reductions, is important to achieve stability. Awards should be at least five years (and perhaps 10-15 years) to enable scientists to focus on research and not administration. They noted that the recently initiated long-term NIH grants were beneficial and should be continued.

II. DISCUSSION OF PRINCIPAL ISSUES

A. Interim Funding

1. Statement of the Issue

Continuity of funding was repeatedly mentioned in testimony as absolutely necessary for productive research. Routine use of interim funding has been considered as a means to address this issue, but, it would require a sizable increase in funds. Hence, its implementation should be carefully scrutinized from two perspectives: the extent to which it would accomplish the desired objective, and the negative impact this would have on companion recommendations (i.e., to eliminate or minimize reduction of grant awards and to increase the funding rate of approved scientifically meritorious applications).

On its face, routine interim support seems plausible and of obvious merit. On the other hand, when the inherent trade-offs are considered, there is concern that the costs of implementation may, in fact, outweigh the benefits. Other approaches to resolve the basic problem of a possible hiatus in funding of ongoing research may be necessary.

2. Background

Circumstances for providing interim support vary across NIH funding units. As the demand for funds in all extramural programs has increased, interim funding has been provided under more and more restrictive conditions. For example, NIDDK provides limited interim support for R01s only when an application has been deferred for additional review or when very unusual conditions pertain (e.g., the need to support a colony of animal models that would otherwise have to be eliminated). Program managers must constantly choose among such alternatives for allocating funds as the interim support of projects with uncertain futures, funding additional competing applications, or minimizing the reductions from recommended levels on all grants. Using NIAID as a case in point, there were 52 unfunded competing renewal research grant applications (R01/R22/R23/R29/R37s) in FY 1988 with priority scores between 141 and 146. The total estimated cost for providing one year of support would be approximately $10 million.

3. Views of Public Witnesses

Witnesses identified what they considered one of the most difficult times for a research team. It is the period when a competing renewal application has been submitted, reviewed, approved, but not funded. The investigator must then prepare and submit an amended application, wait for the review cycle to take its course, and keep the research group together and productive while awaiting new funding--which can often take more than a year. This can lead to the departure of highly trained personnel and the reallocation of space and equipment to other projects. If the amended application finally is funded, the principal investigator must attempt to reconstruct the group and regain the research momentum lost during the period when the project was without funds.

It frequently was suggested that NIH implement special policies and procedures to minimize the time required for the applicant to submit an amended application, for the NIH to review it, and reach a funding decision. This could be achieved by providing interim support during the time that the amended application is under review. The sentiment is that such routine interim support would be a valuable reform that would save a number of important research programs from potential disaster. The costs to implement this policy, even within a narrow zone of consideration, would still be considerable and thereby would significantly decrease funds available for other needs.

4. Status of NIH Activities

The Working Group believes that the current NIH practice of handling requests for interim support on a case-by-case basis may be the best overall approach. Some renewal applications from excellent programs may receive priority scores far from the funding cut-off and yet have flaws that are more amenable to

correction than applications with priority scores closer to the payline but within the zone of consideration. There is no easy way to determine routinely which amended applications are likely to be funded and which are not. New approaches for expediting the review of amended applications are under consideration. DRG is conducting a study of a combined summary statement (COSS) for review of selected applications. It focuses on revisions to the prior application and reviewers' recommendations, and would be attached to the previous summary statement.

The costs of providing interim funding to all approved competing renewal applications beyond the payline would be enormous. More reasonable would be to provide it only for a limited number of applications on the basis of specific criteria, such as those not more than 5 to 10 points beyond the funding cut-off. For such selected applications, interim support could cover only such essential items as salary, supplies, and maintenance of animal colonies.

5. Options for Consideration in Addressing Issue

Alternative solutions to the need for continuity are to encourage principal investigators to submit their renewal applications one or two cycles early to allow time for rereview, if necessary, and to expedite review of selected amended competing renewal applications. Early submission of a renewal application is a feature of NCI's Outstanding Investigator Grant.

The Working Group considered the implications of devising special procedures for expediting receipt and review of amended applications. At issue is the feasibility of such special handling so that these applications could be given initial review during the meeting immediately after the one in which the

Event	Normal Schedule	A Possible Expedited Schedule	Schedule Entailing No Funding Gap
Submission of Renewal	11/1		7/1
Review	2/15		10/1
Summary Statement Available	4/15		12/10
Council Review	5/20		1/20
Submission of Amended Renewal (for suppl. material)	7/1	5/1	1/1
Review	10/1	6/15	3/1
Council Review	1/20	10/1	6/1
Funding	4/1	12/1	7/1

original competing renewal application was reviewed. The timelines presented below illustrate the problem and a possible solution. They use, as an example, a competing renewal application that normally would be submitted on November 1 to renew funding of a project scheduled to expire the following June 30.

The normal cycle, illustrated in the first column, shows that, if an amended application is required and if it is then reviewed during the next normal review cycle, approximately nine months elapse between the time funding ceases (7/1) and the time funding can resume (4/1). The second column illustrates a possible accelerated review of an amendment. It shows that, even with an almost impossibly tight schedule, there is still a 5-month hiatus in funding. The third column shows that, to avoid a gap in funding (and assuming that an amendment to the original application is required), the applicant could submit the original application one round early, and a highly accelerated review of the amendment would be conducted. The accelerated schedules illustrated in the second and third columns are so tight that they would require a number of modifications to the regular application submission and review process. For example, since the accelerated schedule allows only two weeks for the applicant to prepare and submit an amendment, it would have to be a relatively informal response to the critique of the original application, presumably in letter form, which would be reviewed by the study section together with the original application. It would also have to be available immediately to the executive secretary so that it could be sent to the committee at the earliest possible time (thus bypassing the referral process). The review itself would probably have to be abbreviated, perhaps using a mail review rather than the traditional meeting.

Although this procedure might be possible in some instances, the Working Group believes it would present problems if applied to all cases. The interval might be very short between the time that the summary statement of the original competing renewal application is available and when amended material would have to be sent to reviewers. Also, to ask that the second review be conducted on an original application plus supplementary material would place an additional burden on the reviewers and not provide the applicant with a review comparable to that of an integrated, carefully prepared revised application. Nevertheless, the Working Group recommends that a detailed study be conducted to determine whether any general acceleration of the review of amended competing renewal applications could be instituted without seriously compromising the quality of the review of the applications or placing undue strain on the entire initial review system. The percent of all research project grant applications that are revised has increased from 15 percent in FY 1974 to 27 percent in FY 1986.

B. Carryover and No-Cost Extensions

1. Statement of the Issue

To offset the otherwise unstable or unpredictable funding pattern of the last several years, testimony at the regional meetings recommended discretionary use of carryover of funds (unobligated balances), and no-cost extensions by institutions.

2. Background

Historically, NIH has used balances still unobligated at the end of grant periods in three different fashions. One is use of the funds as an offset to the recommended funding for the continuation award. Funds available as balances and used as offsets were $79 million in FY 1987.

A second alternative is that grantees also may receive NIH prior approval to use unobligated balances as carryover for additional expenditures that are above the recommended level of funds for a renewal award. Such requests are usually approved for activities that are not accomplished as planned. Estimates of NIH-wide funds approved for carryover each year are difficult to obtain, but currently this practice is conservative, and a reasonable estimate is $5 million.

Until recently, a third use of unobligated balances was for indirect cost settlement. In the past, NIH adjusted indirect cost awards for rate and base changes. The net amount of funds to meet this requirement was approximately $5-$8 million of current fiscal year funds and $25 million of prior-year funds that were available as unobligated balances at the end of grant projects. A Department of Health and Human Services policy change on October 1, 1987, however, has terminated this settlement process, which absorbed the $25 million that resulted from end-of-project balances. Such balances may not be used for any other purpose if the projects are no longer active.

Collectively, these three administrative practices used more than $100 million of prior balances in FY 1987.

3. Views of Public Witnesses

Much of the testimony at the regional meetings suggested that NIH permit grantees to determine the use of unobligated balances at the local level. Witnesses believed that they could buffer the problems associated with unstable or unpredictable funding, if unobligated balances could be used within the original project. An automatic carryover feature would permit grantees to allocate funds more wisely with the knowledge that they may use the funds in the next budget period for unanticipated expenditures. Carryover would also help buffer the award reductions that occur due to NIH appropriation levels.

No-cost extensions enable institutions and investigators to control the unpredictability of funding patterns. Investigators notified of the uncertain funding status of a competing renewal, could then extend the current project and continue to expend available funds. In this manner, investigators and their institutions would be able to facilitate their own interim support.

4. Status of NIH Activities

Carryover and no-cost extensions are features of the Florida Demonstration Project (FDP) as well as of the Outstanding Investigator Grant, and of the FIRST and MERIT awards. NIH is considering implementing these administrative policies for other grant mechanisms as a result of the very constructive experience with FDP. As one of the five Federal agencies in the FDP, NIH has

received Office of Management and Budget approval for the broader use of these and other administrative policies that would provide significant flexibility for the use of grant funds at the institutional level.

5. Options for Consideration in Addressing Issue

These administrative policies could be implemented for NIH investigator-initiated mechanisms that do not require significant post-award programmatic involvement (R01, R23, R29, R35, R37). However, NIH should maintain its administrative prerogatives for mechanisms that do require significant programmatic involvement, such as those for cooperative agreements (U01) and centers (P30, P50, P60).

Adoption of these administrative changes for regular research grant mechanisms would provide the research community access to approximately $79 million of prior grant balances. This would permit decision-making at the grantee institution to use carryover for unanticipated expenditures; interim support in cases of uncertain funding; and phase-out support at the conclusion of projects. No-cost extensions would be the only legitimate way to continue to expend the $25 million that result from end-of-project balances for research purposes.

However, it should be noted that implementation of these policies will have a significant effect on other NIH fiscal practices. In the past, when resources were sufficient to support funding levels of grants recommended by the study section and without limits on the numbers of awards, a variety of NIH funding practices existed. NIH provided administrative supplements, carryover with prior approval, indirect costs adjustments, and interim and phase-out support with funds. In the current economic climate, NIH and its grantees are struggling to achieve funding close to the recommended level of support for a relatively fixed number of grants. Vesting the authority for the use of unobligated balances with grantees will conserve the funds for the benefit of the individual projects, but will curtail previous NIH practices that were dependent on unobligated balances as a source of funds. However, this policy change could provide grantees with the greatest possible fiscal flexibility and the least burdensome administrative requirements.

C. Full Funding Versus Cut-Backs

1. Statement of the Issue

The decrease in grant award rate from 50 percent in FY 1979 to about 38 percent in FY 1987 is an issue of increasing concern to the scientific community. This decrease has been concomitant over the past several years with a dramatic improvement in the mean priority score. NIH staff, Council meetings, and Chairpersons of DRG Initial Review Groups note with growing concern this change in mean priority score, dismay over nonfunding of applications deemed to be of high scientific merit, and discouragement about the rising contribution of amended applications to the review load (now, at 27 percent in FY 1986, almost double that of a decade ago).

2. Background

As mentioned in previous sections, in the past NIH was able to offer interim support or termination support in the event that a competitive renewal was not funded. In recent years, however, these options have been available only in exceptional circumstances. Applications very close to the payline receive no funding, and research groups are often unable to remain intact during the revision and rereview process. For those applications that are funded and for noncompetitive renewal applications, NIH has been forced to reduce budgets substantially to support continuing projects and to fund new research projects. Thus, the research community is faced with uncertainty of continued funding as well as unanticipated budget cuts both initially and during the period of an award.

3. Views of Public Witnesses

Public witnesses expressed major concerns on this topic. The funding system that NIH practices is perceived responsible for loss of projects of high merit just beyond the payline. These unfunded applications very close to the payline usually are amended and resubmitted. Funding reductions of a substantial nature recently instituted by NIH are seen as especially disruptive to the orderly planning of a research effort. The climate of uncertainty encourages investigators to maintain multiple grants, produces stress and "burn-out" of established investigators, and does little to attract younger investigators to a research career. Several witnesses proposed a funding system that would, in their view, ensure support of a greater number of high-quality biomedical research proposals: a sliding scale in which the higher priority scores would receive 100 percent of recommended costs and lower scores would receive progressively lower percentages, possibly as low as 50 percent. This system of progressive support is perceived to have several potential benefits; more meritorious research projects could be supported than is now possible, support at less than 100 percent would result in slower progress with perhaps slight reduction in quality while providing a period of interim support so that the research group could remain intact during the amendment period, and the number of amended and duplicate applications submitted would be reduced.

4. Status of NIH Activities

Alternative funding strategies, such as the sliding scale, received attention in the late 1970s and early 1980s during a period when NIH appropriations experienced a relative decline. It was used briefly by the National Cancer Institute to fund its center core grants but discontinued as ineffective for many of the reasons noted below. Analyses of the impact of a sliding scale concept by such groups as the Association of American Medical Colleges produced major concerns. These included the integrity of the research project (Is a substantially reduced project identical to the approved project?), the potential for compromise of the peer review system, concerns about investment of public funds in truncated projects, and changes in NIH's traditional support of the most meritorious projects to one of support of the scientist.

To balance available funds with requirements to fund given numbers of competing applications, NIH has applied reductions to all applications regardless of

priority score. Such stabilizing strategies as interim support and orderly termination support, although offered rarely compared to past practice, are still possible on a case-by-case basis.

5. Options for Consideration in Addressing Issue

The assessment of the Working Group is that a generally equitable use of reductions along with the ability to make adjustments on an individual basis offer the most reasonable approach to long-term stability.

Other funding options, such as limiting reductions or applying alternative funding strategies, necessarily require trade-offs in terms of numbers of applications funded and ability of investigators to pursue a meaningful research program. NIH may wish to consider a reassessment of funding options, including those in current use and those developed for consideration at other times. Funding options should be assessed in terms of their applicability in light of the current budgetary climate as well as their impact on the biomedical research community.

D. Long-Term Support

1. Statement of the Issue

Lack of stable funding for biomedical research adversely affects principal investigators, research teams, the ability to carry out long-term scholarly pursuit as well as attract and retain the best young scientists. Funding uncertainty also contributes to administrative burdens at NIH, including overload of the review system by number of amended applications, by investigators attempting to maintain multiple grants as buffers against a funding hiatus, and by an unnecessary increase in scope and complexity of research applications.

2. Background

NIH grants, which were originally seven years in duration, were reduced to five years from the late 1950s to mid-1960s. Length of awards was reduced even further during the late 1960s to an average of close to three years. This reduction eventually resulted in an increased burden on the investigator, the institution, and the NIH administrative system.

3. Views of Public Witnesses

Comments of public witnesses were related to the impact of uncertain funding for research and the need for long-term support of research, long-term stability, and continuity of funding. Witnesses often referred to the vital role of a stable funding climate in a career of scholarly pursuit and in attracting and keeping new generations of basic and clinical investigators. Uncertainty about funding also was cited as a partial explanation for the increase in review workload and, in part, for increases in the average cost of grants.

Suggestions for a solution to this problem included: action by NIH to extend award periods; use of no-cost extensions; more extensive use of Biomedical Research Support Grants to provide stability; increase in use of interim funding; and increase in NIH appropriations, either as a percentage of the Federal budget or linked to national health care expenditure as an entitlement.

Some misperceptions by the scientific community surfaced in the context of comments addressing long-term stability. These indicated lack of awareness of the recent striking increase in the average duration of a project. This is a direct result of positive action by NIH, including study section education and Council oversight regarding favorably recommended applications reduced in years by study sections as well as the recent introduction of several awards of 7- and 10-year duration.

4. Status of NIH Activities

In the early 1980s, NIH began a concerted effort to deal with short project periods and the resulting destabilization of the scientific community. Additional instructions requiring carefully documented justification of reductions in project periods were given to study sections. Further, National Advisory Councils were educated in their role of overseeing this process. Other NIH actions, such as implementation of the Outstanding Investigator Award and the Javits' Award, have affected project periods favorably. Of recent note is the initiation of the FIRST and MERIT awards in the mid-1980s. Both of these awards were designed specifically to provide the long-term stability requested in the testimony. The FIRST award, made for five years, is nonrenewable and provides NIH with an opportunity to reevaluate the younger scientist after a stable period of development. The MERIT award, which weighs past accomplishments and future promise of established investigators, provides a funding period of up to ten years with minimal renewal requirements.

As a result of these actions, there was an increase in the average length of project period from 3.15 years prior to 1980 to 3.8 years in 1987. Funded applications for five years of support constituted only 20 percent of the pool from 1982 to 1984; 3-year project periods constituted over 60 percent of funded applications during that same period. Data from 1987 show that 5-year and 3-year awards now each constitute 43 percent of the total. Reductions in project periods are fully and carefully justified.

A review of recent NIH actions with respect to providing long-term support shows clearly that the trend toward longer awards is now well established. It appears from the testimony that the scientific community may not be generally aware of recent trends in lengths of awards, the availability of no-cost extensions in the final year of funding, or the advisability of submitting competing renewal applications in time to permit the submission of an amended application if necessary.

The community eloquently addressed the need for long-term stability in these hearings and, as seen above, NIH has responded positively. It is important to recognize, however, that measures to provide long-term stability during periods of modest growth of NIH resources will necessarily have consequences for the funding of new and competing awards in the future. Longer project periods in

combination with the higher-than-anticipated future-year funding increases will necessarily increase the commitment base. Thus, the current balance between future commitments and ability to fund new and competing applications may be unduly compromised.

5. Options for Consideration in Addressing Issue

The Working Group recommends that the potential role of Biomedical Research Support Grants in the stabilization of the biomedical research community deserves study. In particular, it would be important to ascertain whether the current use of these funds promotes stability and to determine possibilities for their expanded application in this regard.

III. CONCLUSIONS AND SUMMARY REMARKS

A. Interim Funding

Continuity of funding is viewed by the scientific community as absolutely necessary for productive research. Many witnesses emphasized the difficulties encountered by research teams when competing continuation applications are not funded. Loss of research momentum or even disbandment of the research team often results from an amendment and resubmission period. The Working Group recognizes the importance of interim funding to the research team but is also cognizant of the negative effect of widespread provision of interim support. It was concluded that the best overall approach is the current practice, that of handling requests for interim support on a case-by-case basis. Individual attention to cases of special need and consideration based on specific criteria, in addition to a general policy of encouraging grantees to submit renewal applications one or two cycles early, would seem to provide maximum opportunity for continuity of funding in the current framework.

An option for consideration, which would address the need of the community for interim support as well as the need to reduce the growing burden of amended applications in the review system, combines early submission of an amended competing continuation application with accelerated review of an abbreviated response to the initial review. It is obvious that this proposal would require substantial additional study to assess the changes in review procedures necessary for implementation as well as to determine those applications to which this could be applied.

B. Carryover and No-Cost Extensions

Many of those who testified at the regional meetings mentioned the disruption to a research program caused by the unstable and unpredictable funding patterns of the last several years. A suggestion for minimizing the negative impact of uncertain funding was the use of unobligated balances to cover unanticipated expenditures and buffer any reductions in the recommended level of the grant award. Carryover and no-cost extensions are features of the Florida Demonstration Project (FDP) and are provisions of recently implemented long-term NIH grants. As a result of the FDP experience, NIH is considering implemention of carryover and no-cost extension provisions for other investigator-initiated grant awards. The Working Group noted that these

features will provide grantees with the greatest possible fiscal flexibility and the least burdensome administrative requirements.

C. Full Funding Versus Cut-Backs

Testimony revealed widespread concern about the low current award rate for NIH grants coupled with the inability to provide sufficient interim or termination support. Applications close to the payline receive no funding, often resulting in disbandment of research groups. The resulting climate of stress and disillusionment has a major negative impact on the biomedical research community. The Working Group recognized the problems encountered by the community and recommended areas for action or further study. Taken as a whole, the current practice of generally equal application of reductions along with the ability to make adjustments on an individual basis was believed to be the most equitable. It is recommended, however, that NIH assess possible other funding options, and their impact on the biomedical research community and applicability to the current budgetary climate. Several mechanisms to reduce the impact of a period of non-funding already exist, such as submission of competing renewal applications in time to permit a revision and carryover privileges at the end of a grant period. The community should be made generally more aware of these options both by guidance from well-informed NIH staff and by other routes, such as meetings and publications. The Working Group suggests that these reports, prepared for the Advisory Committee of the Director, be disseminated to NIH staff and the community.

D. Long-Term Support

Testimony consistently alluded to the importance of long-term support in the biomedical research community. A review of activities shows that the NIH has been extraordinarily responsive to this need in the past several years. This has resulted in impressive gains in average length of project periods as well as the availability of several awards of seven and ten year duration developed for both the new and established investigator. These efforts should be continued. The Working Group believed that, unless major increases in NIH appropriations occurred, further substantial activity along these lines might unduly compromise the current balance between future commitments and the ability to fund new and competing awards. The suggestion by several witnesses that Biomedical Research Support Grants might be used more effectively to stabilize the biomedical research community was thought to deserve further study.

Advisory Committee to the Director

Summary of Testimony

on

Indirect Costs

June 27-28, 1988

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INDIRECT COSTS

I. Introduction

A. General Overview

Witnesses expressed concerns regarding indirect costs at each regional meeting of the Advisory Committee to the Director, NIH. Generally, the concerns ranged from the effect of high indirect costs rates on merit review to full reimbursement of the Federal share of research overhead. The principal themes of the testimony are elaborated in the body of this report, but the issues included discussion of the disparity of indirect costs rates and the bases upon which they are calculated; the need for upgrading research facilities and the impact on indirect costs; the lack of understanding of indirect costs policy and practice and the tremendous need for an education program; and the impact on the research program by changes in indirect costs negotiation policy and practices. The following section is a history of the development of indirect costs policy which gives rise to these issues.

B. History of Reimbursement of Indirect Costs

The payment of indirect costs, or "overhead", on grants by the National Institutes of Health (NIH) has a long history. When the Committee on Medical Research of the Office of Scientific Research and Development (OSRD) was about to liquidate its program at the end of 1945, it was decided that the Public Health Service (PHS) was the logical agency to support the fifty or so projects that were continuing.

At the first meeting of the National Advisory Health Council (NAHC) in March 1946, the question of indirect costs generated considerable discussion. The NAHC was fully aware that the OSRD had provided an allowance for indirect costs when the government purchased ideas and services of university staff. The PHS, on the other hand, was assisting scientists in the pursuit of their own research projects. At this meeting, the NAHC was unanimous in its decision that no overhead allowance whatsoever should be provided; universities should submit requests for support on only those projects for which they were able and willing to provide certain assistance, such as overhead.

As a result of this decision, several university officials came to the NIH to discuss the matter and press for reconsideration. The NIH was persuaded to prepare a statement on overhead for presentation to the NAHC, and at its May 1946 meeting, the NAHC agreed that there might be instances when an overhead payment of 7 or 8 percent would be appropriate. However, it was not until the September

1946 meeting of the NAHC that agreement was reached on a policy of applying a rate of 8 percent for indirect costs on research grants, effective January 1, 1947.

As institutional overhead costs increased, grantee institutions requested higher rates. This pressure resulted in an administrative decision to increase the rate to 15 percent for research grants effective July 1, 1955. The indirect costs rate of 8 percent for training grants was retained and, in fact, remains in effect today.
In the Fiscal Year (FY) 1958 Departmental Appropriations Act, the Congress codified this practice with a provision which stated that a grantee could not be paid an amount in excess of 15 percent for indirect expenses.

This rate continued without change until it was raised to 20 percent in the FY 1963 Appropriations Act. In considering this change, the House and Senate Appropriations Committee Conference Report of July 31, 1962 stated, "The Committee of Conference desires that the Department carefully review the expenses incurred under research grants with a view to allowing no more than the actual expenses for indirect costs in cases where such indirect costs amount to no more than 20% of the direct costs."

This required an awareness of actual indirect costs. Because of the practice of providing a flat allowance actual indirect costs rates for each grantee institution were not known. The exceptions were those few grantees whose actual rates had been developed by the Department of Defense and the Atomic Energy Commission in connection with the performance of contracts.

During the years 1963-1966, the NIH worked diligently to establish appropriate indirect costs rates for its grantees. However, it was soon realized that other elements of the Department were using those rates, for example, the rest of the PHS and the Office of Education. With this realization, the responsibility for negotiation of indirect costs rates was transferred in 1966 from the NIH to the Office of the Assistant Secretary, Comptroller, Department of Health, Education, and Welfare. Today, "cognizant agencies", such as the Department of Health and Human Services and the Department of Defense, negotiate indirect costs rates for recipient organizations.

In 1965, the Report to the President by the "Wooldridge" Committee presented a clear statement on indirect costs:

> "We believe that steps should be taken to make it easier for all involved - scientists, administrators, and government representatives - to obtain a clear picture of all costs legitimately associated with each NIH-supported

> project. Reliance upon an arbitrary indirect cost percentage should be abandoned. Instead, each institution should be encouraged to present a complete accounting of all the costs of 'doing business' that it can support as chargeable or allocable to the project in question . . . Every attempt should be made to destroy the present rather widespread misconception that certain expenses are somehow legitimate and therefore fully reimbursable while other costs, being of questionable validity, are entitled to receive only partial recognition."

The Department and the NIH accepted the recommendation of the Wooldridge Committee. With the passage of the Appropriations Act of 1966, the Department implemented a policy of full reimbursement of indirect costs under research project grants. It should be noted that the Office of Management and Budget Circular No. A-21, "Cost Principles for Educational Institutions", was "... designed to provide that the Federal Government bear its fair share of total costs . . ." These OMB cost principles provide the fundamental guidance on the allowability of costs and their allocation as direct or indirect charges.

The Department's reimbursement policy, which was in force through FY 1987, insured that regardless of the amount awarded for indirect costs at the time the grant was issued, grantee institutions could recover their actual outlays for indirect costs. Reimbursement occurred by applying the grantees' negotiated permanent rate, after it was finalized, to the actual direct costs "base" expenditures.

Beginning October 1, 1987 (FY 1988), the Department revised its indirect costs policy in response to a recommendation by the Office of Science and Technology Policy that HHS adopt the reimbursement practices of the National Science Foundation. The major changes were that (1) research grant applicants must show the amounts of both direct and indirect costs requested; (2) the total amount awarded (direct plus indirect costs) constitutes the maximum reimbursable amount under the grant; and (3) grantees are authorized rebudgeting between direct and indirect costs (in either direction) without prior approval.

There are several attachments at the end of this report. Appendix A is a chronology of important indirect costs policy events. Appendix B displays the rates of indirect costs dollars to total dollars awarded for the FY period from 1972 through 1988 (estimated). This table reflects that during this 17-year period, indirect costs have increased 10.7 percentage points, or 52.15 percent. Since 1984, however, the rate of indirect costs awarded has remained stable at 31.3 percent of total dollars awarded.

This "rate" should not be confused with institutional indirect costs rates which are expressed as a percentage of indirect costs to direct costs. Appendix C is a breakdown of the components of indirect and indirect costs to total expenditures.

C. Summary Analysis of Public Testimony on Indirect Costs

Views on indirect costs were a reflection of the presenters positions in the scientific or institutional hierarchies. High level officials in administration urged that the Government adopt a policy which would permit an adequate recovery of indirect costs, thus assuring the availability of sufficient facilities and support services for the conduct of research in the nation's research institutions. Research investigators, for the most part, thought that indirect cost rates were higher than they should be and that their grants received relatively few benefits from certain elements of the indirect cost rate, for example, departmental administration costs, and operations and maintenance expenses.

A common theme in the suggestions of institutional officials was the need to inform research faculty and Government administrators fully concerning the benefits accruing to sponsored research through the reimbursement of indirect costs. They also cited the need for Federal support of the research infrastructure. Many recommendations emerged from the testimony of research faculty. One of these was that institutions should make a special effort to keep indirect cost rates low in order to maximize the results of sponsored research projects. Another faculty suggestion was that institutions consider allocating indirect cost revenues back to the departments for their use in expanding the research infrastructure. According to investigators, such action would demonstrate that they are actually deriving tangible benefits from indirect costs expenditures.

Representatives from institutions with small research bases addressed the difficulties of maintaining stable indirect costs reimbursement. They indicated that this is expecially difficult in light of the new Department of Health and Human Services policy which caps the maximum reimbursement at the time of the award. The witness expressed that this policy can have a disproportionate effect when the rate changes or an institution loses one or two awards, since certain costs are fixed and do not change with the number of research projects. Less intensive research institutions need to seek ways to stabilize the large fluctuations in demands for services and their reimbursement from external sponsors.

II. Discussion of Principal Issues

A. Indirect Costs - Impact on Competition

Statement of the Issue

Concern was expressed during the public discussion that there may be an implicit tendency by study sections to favor applications with low indirect costs compared to those with higher costs. While the witnesses were aware that review groups are directed to provide advice on only the scientific merit of applications, they are concerned that it is becoming extremely difficult to ignore budgetary issues as the competition for research dollars becomes even more strenuous.

Background

Prior to October 1, 1987, grant applications reflected only the direct costs requested for the research project. While peer reviewers make recommendations on direct cost budgetary adjustments, they have not had the occasion to be concerned about the total cost implications and the variability of indirect costs rates among institutions. However, as a result of a revision to the Department of Health and Human Services policy on indirect costs reimbursement, grant applications must present both the direct and total costs proposed for all years of the project. This makes the impact of indirect costs immediately apparent. Applications to the National Science Foundation have required indirect costs information for many years. The revision to the indirect policy states that reviewers may not change indirect costs rates or restrict their application. Executive Secretaries and Chairpersons of study sections have been carefully instructed to prevent any discussion of indirect costs within the determination of the scientific merit of the application.

Research investigators, who may not be aware of these precautions, are very concerned that the indirect costs rate of their institution may affect the competitiveness of their proposals. They are concerned that differences in public versus private institutional rates, or low cost versus high cost institutions, will be taken into account in the assessment of the scientific merit. Stanford University has just completed a very comprehensive review of this subject from the perspective of that campus and their faculty concerns (see bibliography).

Views of the Witnesses

The background section summarizes the sentiment of many of the remarks. One witness stated that it is extremely

difficult for members of study sections to ignore budgetary issues, since they must make an effort ... "to squeeze more research support out of dwindling resources."

Other witnesses suggested that total costs should be considered in merit review to provide an advantage to "low cost" institutions and to make more funds available for research.

Status of NIH Activities

The policy of the NIH is that study section members may not change the applicant's indirect costs rate or the amount of the indirect costs award. Executive Secretaries and Chairpersons of study sections have been briefed on this matter. Awarding unit staff minimize the consideration of total award costs when making funding decisions. For the most part, applications are considered entirely on scientific merit and program relevance. Most awarding units consider only the recommended direct costs and an estimated average of indirect costs when making funding decisions. After the award decision, the most current institutional indirect costs rate is applied to the direct costs to compute the total award.

Options

The DHHS policy, which requires that both direct and total costs appear on grant applications, is too new to determine its impact on competitiveness. The NIH may review this issue at the end of one year to analyze the effect of the indirect costs information on the review process. If any effect is determined, appropriate policy alternatives may need to be identified.

B. Disparity of Rates and Bases

Statement of the Issue

There is considerable concern and misunderstanding about why indirect costs rates vary so widely, not just regionally but even within states or cities. For example, one private, New England university's rate is 76 percent and another private one in the same region is 56 percent.

Background

Studies performed in recent years have revealed that rates differ for a variety of reasons.

Each university has a unique and shifting mix of resources and services which support research activities. The location, age, operation and maintenance, and utilities of research facilities are examples of costs which have significant impact on the composition of the indirect costs rate(s). The adoption of either the "use allowance" or the "depreciation" method for recovering the costs of facilities may have a significant effect on rate volatility. The use allowance provision is two percent of acquisition cost for facilities and six and two-thirds percent for equipment. The amount calculated under the depreciation method is determined according to the estimated useful life of the property.

Research costs sometimes vary from one academic discipline to another. A project in health may require extensive facilities, sensitive equipment, and precise environmental control, all of which are more costly than those for other types of research projects requiring little space and support services. Institutions performing research in many disciplines have different total research requirements from those specializing in one research area.

Procedures for allocating indirect costs vary from university to university. Costs which some universities classify as direct costs are treated by others as indirect costs. For example, one organization may charge secretarial salaries as direct costs, conversely, another institution may recover secretarial costs through indirect costs. As more items are classified as direct costs, the indirect costs "pools" decrease, the direct costs "base" increases, and the rate becomes smaller.

The base selected to distribute indirect costs has a major effect on the indirect costs rate. Grantee organizations use types of bases - modified total direct costs (MTDC) or salaries and wages (S&W). Research-intensive organizations

generally use an MTDC base, the most common form of which is total direct costs less equipment, alterations and renovations, patient care costs, and that amount exceeding $25,000 on each individual subcontract. Smaller organizations generally use an S&W base, including all or various combinations of fringe benefits for example, Social Security taxes, retirement contributions, group insurance, and vacation, holiday, and sick leave pay. In fact, there are about 100 different direct costs bases, mainly variations of both MTDC and S&W. This makes rate analyses and comparisons extremely difficult.

Some institutions are more aggressive than others in pursuing indirect costs recovery. Greater recovery requires special studies, and the cost to the institution of obtaining those studies is significant. Some institutions elect not to conduct these studies, believing that the costs of the studies could exceed expected revenue increases.

Views of the Witnesses

The testimony indicated the lack of understanding of indirect costs and their benefits to research, as well as misconceptions concerning how indirect costs rates are calculated. There was also some indication of the rate "trap," that is, the attempt to make comparisons of institutional efficiency based on indirect costs rates alone.

Other testimony sought to explain rate differences and efficiency by defining the factors affecting variability; such as, utility costs, building type and age, type of research and institution; and sophistication of accounting systems.

Options

Public testimony highlights the perception that the wide variation in indirect costs rates can be reduced through standardized accounting practices.

One proposal calls for establishing NIH-mandated minimum standards of research support in areas that are relatively quantifiable; for example, sterilizing facilities, radiation safety, distilled water, building maintenance, grant bookkeeping, and equipment repair facilities. Institutions would negotiate for reimbursement of these costs along with any other justifiable costs. This proposal is expected tc result in greater uniformity of services and a specific level of reliable support for investigators.

Another proposal recommends standardizing indirect costs

rates based on specific guidelines for how indirect costs may be used. Standardization is to include regional factors associated with the costs of research; for example, heating, cooling, and rental, and would target an indirect costs rate of 40 to 50 percent for all institutions. A cap on the difference between the highest and lowest indirect costs rate (the difference not to exceed 15 percent) would minimize wide disparities among institutions.

One witness contends that he is not able to obtain adequate clerical and administrative services for his grants because peer reviewers eliminate direct salaries proposed to support those services on the basis that those costs are or should be included in indirect costs. Since his institution refuses to use institutional funds for clerical and administrative services deleted by reviewers, he proposes that investigators be given the option of proposing direct costs for such support with commensurate reductions in indirect costs.

C. Indirect Costs - A Need for Education

Statement of the Issue

The testimony of the witnesses indicates the lack of information and the misconceptions about indirect costs. There is considerable confusion among faculty regarding actual institutional overhead expenses, rate negotiations, the perceived implications of indirect costs rates on peer review, the treatment of indirect costs recovery as a revenue within the institution, and the disparity of rates among institutions. The system is complex and highly centralized, with the principal actors being a few experts within institutions and the Federal Government. So, it is not unusual that faculty and many NIH staff, for that matter, are unsophisticated regarding the intricacies of indirect costs. In fact, the system has protected investigators so that they are free of this administrative burden to concentrate on their research. However, we are paying a price -- and that price is a lack of basic understanding about the system of indirect costs and the underlying mistrust that results from the lack of information. The result is often the perception of an adversarial relationship between faculty and administrators.

Background

The identification and negotiation of indirect costs is a highly complicated process which is governed by Office of Management and Budget cost principles and agency policy. The task is ordinarily left to a few experts in institutional business offices and staff of the Federal agency that negotiates the rate. Most often faculty have little or no involvement in the issue. As the system of indirect costs recovery and research institutions have grown more complex, it has become more difficult for research investigators to identify and understand all of the organizational services which are provided through this financial mechanism in support of their research. Part of the confusion regarding indirect costs exists because of the different ways in which indirect costs recovery is treated as revenue to the institution. One approach treats it entirely as unrestricted income and uses it to offset all costs of the institution without regard to the functions that generated the cost or the income. Another approach reallocates certain portions of the recovery back to the organizational component that generated the income, including funds for pilot projects or for small equipment purchases.

The use of indirect costs income is not governed by Federal guidelines and none of the approaches are inherently right or wrong. However, it is quite evident from the testimony that these different approaches create varying impressions among faculty. The first approach treats indirect costs the same as all other sources of income but in the process diminishes the visible benefit to research. The second approach heightens the benefits to research but minimizes its essential requirement as an income to offset real institutional expenditures. Naive observers, both within and without an institution, may not understand the variety of approaches and their implications.

For this and other reasons, it becomes imperative, as several of the regional witnesses indicated, to conduct an education program regarding the composition of indirect costs and the mechanism of reimbursement of these costs by sponsors of research at the institution.

Views of the Witnesses

Testimony at the Regional meetings indicated a wide range of understanding of the indirect costs topic -- from unsophisticated to expert. The following are examples of some of the views on the subject.

One witness suggested that low rates at some institutions indicate cost efficiency and suggested that rates should be standardized between forty and fifty percent with deviations only for energy costs.

Another witness stated that some of the services charged to indirect costs are never provided, such as administrative support personnel for the project, even though "additional" indirect costs have been received. This witness further stated that upper-level administration may plan certain uses for indirect funds which would be different from those the principal investigator would find best for the project.

Another witness stated that certain institutions "pass-back" a portion of indirect costs to investigators for additional project resources. The witness felt this practice gave unfair advantage to investigators in those institutions and that, if this part of the cost recovery were eliminated, indirect costs rates would be more comparable among institutions.

At least two witnesses suggested the need for education in this area. One witness indicated that there are legitimate reasons for escalating rates and differences in rates among institutions. He cited the need for continuing education among faculty with respect to the nature of indirect costs, their contribution to the overall operation of the

university, and their relationship to adequate funding for basic research. Another witness suggested that the general problems associated with indirect costs should be addressed by all parties to the research enterprise, for example, scientists, and other personnel of universities and the Federal Government.

Status of NIH Activities

The NIH, other Federal agencies, and many recipient institutions currently conduct a variety of seminars on the subject of indirect costs. It is covered within the NIH Regional Seminar for Grants Administration which is held twice a year around the country. The topic is the subject of intense coverage within many professional association meetings. Many research organizations also have a variety of approaches to educating their staff on the subject. However, the tenor of the testimony at the regional meetings suggests an even more concerted national educational program as well as more involvement of faculty in discussion of, indirect costs policy within the institution.

Options

One option is to develop instructional materials to educate all parties about indirect costs, their composition, their reimbursement, and their use within the institution. These materials could be prepared from both the institutional and the Federal point of view and be utilized in courses for investigators and university and Federal administrators. Model presentations could be developed to which each institution could add the specifics of their indirect costs and expenditures for overhead. The recent study conducted by Stanford University, "1986-1987 Decanal Indirect Cost Study," which included faculty on the study team, could be used as a sample approach. The bibliography that is an attachment to this report also contains some helpful background materials. The NIH should conduct similar courses for program staff, grants managers, and executive secretaries of review groups.

D. Indirect Costs - Support of the Infrastructure

Statement of the Issue

Several of the witnesses commented on the need for indirect costs revenues to continue to support the research infrastructure. This relates to the indirect costs dollars that are currently used to support buildings and facilities. Institutions recover a prorated share of the costs of construction, renovation, and alteration by including either depreciation or use allowances as part of the indirect costs claimed on grants. Additionally, operations and maintenance costs included in the indirect costs rate include renovations and repairs to buildings, facilities, and equipment. This issue is being addressed in an independent report to the Advisory Committee to the Director, however, it is important to highlight that part of the discussion relating to indirect costs.

Background

The negotiation of indirect costs rates includes a calculation for both the routine operations and maintenance of facilities as well as either depreciation or use allowance. Operations and maintenance includes non-capital renovation and maintenance as well as utilities, insurance, fire protection, safety, and other plant operation expenses. The depreciation on buildings and equipment may be taken one of two ways. Use allowance permits six and two-thirds percent of the cost of equipment and two percent of the cost of facilities. Depreciation permits an actual proration of costs over the useful life of the building, however, specific accounting records must be maintained for each facility which is charged-off in this fashion. For this reason, many institutions choose the use allowance methodology.

Operations and maintenance expenses and depreciation or use allowance make up a significant component of each institution's indirect costs rate structure (see appendix C). A revision to the cost principles for educational institutions in 1982 also permitted interest charges for equipment and facilities to be included in indirect costs.

Views of the Witnesses

Concern was expressed during the public discussion that the "crumbling" infrastructure was causing indirect costs rates to increase and that specific action is required to rebuild this nation's research facilities. One commentator noted that the rapid and massive requirement to develop AIDS centers has put a unique pressure on indirect costs rates. Specifically, buildings which were scheduled to be

demolished have been retained and renovated at great cost to provide laboratories for AIDS researchers.

Other commentators described how important it is for the administration to understand the vital role of indirect costs in maintaining the necessary facilities which enable research to flourish in this nation. Faculty witnesses commented that it is not always evident how much the institution is putting back into facilities and equipment from indirect costs revenues. They were concerned that if this is not done, there will not be sufficient facilities to carry out research.

Options

Specific options for funding the research infrastructure range from increasing the use allowance to providing funds for construction grants (see Facilities Report to the Advisory Committee to the Director). However, any option must recognize that increased funding in one area may mean decreased funding in another. As the facilities and equipment base expands and depreciation or use allowances are increased, indirect costs rates will escalate. The effect of this in the research grant pool will translate to more funds for indirect costs and fewer dollars for the direct costs of research. This will heighten the competition for project grants in what is an already extremely competitive environment.

III. Conclusions

The public witnesses offered many options for the simplification and standardization of indirect costs recovery. While the sentiment for these may have emerged primarily from the faculty testimony, certainly all parties, grantees and sponsors alike, would have much to gain from a more simplified indirect costs reimbursement that continues to provide equitable support of the research infrastructure.

Many of the individual options have merit and deserve further exploration, which is not possible within the confines of this report.

The options presented here are a distillation of the testimony of the public witnesses and are offered to the Advisory Committee to the Director for their consideration.

A. NIH Annual Review of Indirect Costs

It is somewhat remarkable that one of the main themes that emerged in each of the regional meetings of the Advisory Committee to the Director was indirect costs. The fact that the NIH expended $1.3 billion for indirect costs in Fiscal Year 1987 makes it an important issue. But, perhaps even more important than the volume of overhead support, is the sentiment it produces in every sector of Federally sponsored programs. Representatives of every function in the research community have an important stake in the indirect costs issue, be they faculty, institutional administrators, or staff of Federal agencies. The ongoing discussion among the important players who can make an impact on this issue may, over time, play a beneficial role in keeping these costs within bounds and simplifying the system to the benefit of all parties. There may well be a coincidence between the leveling off of indirect costs to about 31 percent of total costs in recent years and the "spotlighting" of this issue by Professor Kenneth Brown, while a member of the National Advisory Eye Council, and others in the early 1980s (see bibliography). One of the healthy constraints on these costs may be the pressures brought to bear by informed participants in the process, such as, NIH staff, researchers, and institutional and public officials.

In fact, one of the potential problems in the current system is the separation of indirect costs negotiation and policy from extramural program funding. The principal policy on indirect costs reimbursement is established by the Office of Management and Budget in the various cost principles (Circular A-21 for education institutions). Indirect costs rate negotiations, including the determinations that costs should be treated as either direct or indirect, are usually

conducted by cognizant agency experts in regional offices. Only the actual award of indirect costs occurs at the program level which also determines the direct costs award. This process removes the awareness of and responsibility for indirect costs issues from the scientific program, much like removing quality control from the assembly line.

Therefore, one option is that the Deputy Director for Extramural Research, NIH, conduct an annual review of the public policy issues which impact indirect costs. This office could, on an annual basis, provide a report to the Advisory Committee to the Director, NIH, that summarizes the major events and changes in Federal policy, cost trends, and recipient practices that influence the indirect costs issue. Several areas could be monitored specifically over the next few years. One area is the change in amounts provided for depreciation and use allowances and the impact of interest charges for facilities. Another is the shift between direct and indirect costs, as is taking place, in animal per diem rates. A third area is the effect of indirect costs on average grant costs trends and the amount of funds provided for direct costs.

The Advisory Committee to the Director could provide appropriate recommendations on these issues to the Director, NIH, who could then provide the necessary feedback on these reports to BID Directors, their councils and boards, NIH staff, and other public officials. In this fashion, the NIH may take a more proactive posture in the development of national indirect costs policy.

B. Education Program

Another option in keeping with much of the public testimony is to develop an education program on indirect costs for investigators and Federal and institutional administrators. Basic materials could be developed to identify components of overhead costs, guidelines for reimbursement, and their use as a revenue within the institution. These materials could address the subject from both the Federal and institutional point of view. Each institution could add the specifics of their indirect costs expenditures and rate composition. This could serve as the basis for ongoing dialogue within the institution on the subject of indirect costs policy. The NIH could offer this course to its own staff, grants managers, program administrators, and executive secretaries for review.

The Director, NIH, could request one of the national professional organizations such as the Association of American Universities, the Council on Governmental Relations, the Society for Research Administrators, or the National Council of University Research Administrators to

undertake this important project. An educational effort of this kind could raise the level of information about this subject for all parties and reduce the potential for misunderstandings and conflict within the community.

C. Future Studies and Demonstrations of Indirect Costs

A third option is that the Director, NIH encourage future studies of the various proposals presented by witnesses at the Regional meetings. Some of these proposals deserve serious consideration and possible demonstration or experimentation under the auspices of a third party organization of national stature. Under such sponsorship, Federal agencies and research institutions could collaboratively assess the advantages of standardization and simplification of the indirect costs reimbursement process. The Association of American Universities (AAU) is currently conducting a study of indirect costs. Their committee which is chaired by Dr. Cornelius Pings, Provost, University of Southern California, expects to issue its report in July, 1988. It may be that the recommendations of the Advisory Committee to the Director, NIH and those of the AAU begin to identify a consensus for future demonstrations of these proposals.

The goal of such a review or demonstration should be equivalence, not a single, standard rate. The greatest need is for equity and comparability of rate composition and the research base. Proposals could be developed to standardize the distribution between direct and indirect costs and the allocation of costs to the research base. Standards could be developed for one method of rate application; that may be either Modified Total Direct Costs (MTDC) or Salaries and Wages (S&W), eliminating the current variety within these approaches. A demonstration could determine the potential for the use of standard formulas within certain indirect costs components, such as Use Allowance, General Administration, and Departmental Administration, in order to derive equivalency and equity of reimbursement. A study could also address the issue of equal reimbursement by all sponsors of research, Federal, industry, foundations, and others, so that all parties pay their fair share. Finally, a study may explore standard, simplified rates for less intensive research institutions, where it may not be worthwhile to engage in a sophisticated rate development process.

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Appendices

Appendix A

CHRONOLOGY OF IMPORTANT INDIRECT COSTS EVENTS

Prior to FY 1956	Indirect costs rate 8% of total direct costs (TDC)
FY 1956 - FY 1962	Research grants - rate increased to 15% of TDC Training/career development - rate remained at 8% of TDC
FY 1963 - FY 1965	Research grants - rate increased to 20% of TDC or actual rate, if less Training/career development - rate remained at 8% of TDC (today also 8%)
FY 1966 - FY 1985	DHHS Appropriations Act imposed cost sharing on research grants
FY 1966 - FY 1987	DHHS policy permitted full reimbursement of indirect costs for research project grants subject to: o Indirect costs rate agreement o Cost sharing agreement (requirement expired February 1986) o Availability of funds
March 1979	Cost Principles for Educational Institutions reissued as OMB Circular No. A-21
August 1982	A-21 revised to allow interest on buildings and equipment acquired or completed after June 1982
December 1980	A-21 revised to establish indirect costs allowance of 3.6% of MTDC for faculty administrative effort after June 1987
October 1987	DHHS policy changed to: o Require grant applications to show both direct and indirect costs requested o Provide that total amount awarded (direct plus indirect costs) is maximum reimbursable amount o Authorize virtually complete grantee rebudgeting between direct and indirect costs (in either direction) without prior approval

Appendix B

NATIONAL INSTITUTES OF HEALTH
STATISTICAL DATA-RESEARCH GRANTS
PERCENTAGE OF INDIRECT COSTS TO TOTAL DOLLARS AWARDED
CURRENT DOLLARS
(DOLLARS IN THOUSANDS)

FISCAL YEAR	DIRECT COST AWARDED	INDIRECT COST AWARDED	TOTAL COST	PERCENTAG OF INDIRECT TO TOTAL C
1972	$641,865	$166,243	$808,108	20.6
1973	614,078	185,587	799,665	23.2
1974	745,547	240,191	985,738	24.4
1975	741,558	258,938	1,000,496	25.9
1976	1,058,466	386,164	1,444,630	26.7
1977	961,162	359,140	1,320,302	27.2
1978	1,112,973	416,093	1,529,066	27.2
1979	1,331,722	512,279	1,844,001	27.8
1980	1,463,768	586,306	2,050,074	28.6
1981	1,568,995	655,143	2,224,138	29.5
1982	1,610,679	689,855	2,300,534	30.0
1983	1,793,207	791,580	2,584,787	30.6
1984	2,036,639	921,627	2,958,266	31.2
1985	2,343,216	1,069,707	3,412,923	31.3
1986	2,443,087	1,119,115	3,562,202	31.4
1987	2,876,830	1,311,539	4,188,369	31.3
1988 1/	3,117,918	1,420,536	4,538,454	31.3
INCREASE FROM FYs 1972-1988	$2,476,053	$1,254,293	$3,730,346	10.7
PERCENT OF INCREASE	385.76%	754.49%	461.61%	52.15%

1/ SOURCE: FY 1988 CONGRESSIONAL BRIEFING BOOK

PREPARED BY: FEDERAL ASSISTANCE
ACCOUNTING BRANCH. DI
DATE: MAY 3. 1988

REPORT OF
WORKING GROUP
ON
MINORITIES
IN
BIOMEDICAL RESEARCH

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REPORT OF THE WORKING GROUP ON MINORITIES IN BIOMEDICAL RESEARCH

EXECUTIVE SUMMARY

At the regional meetings of the Advisory Committee to the Director, NIH, testimony was presented by concerned individuals and organizations regarding the underrepresentation of minorities in biomedical research. Although the National Institutes of Health (NIH) initiated efforts to address this problem in 1971, when several programs were developed (i.e., the Division of Research Resources' Minority Biomedical Research Support Program, and the National Institute of General Medical Sciences' Minority Access to Research Careers Program), it was pointed out by presenters that its efforts have to be increased. It is no longer sufficient just to increase opportunities, but rather, there must be an effort to specifically address the national problem of a declining scientific manpower pool and an increasing dependence on foreign students in some fields (i.e., biochemistry). While the solutions are not simple, a number of good suggestions did emerge from the discussions at these regional meetings.

This paper, prepared for the June 27-28, 1988, meeting of the Advisory Committee to the Director, NIH, presents an overview of the statistics regarding minority biomedical scientists in the United States; a summary of the NIH programs designed to increase the number of biomedical researchers who are members of minority groups; and presents the following options for consideration for immediate action and for long-range planning:

Options for consideration for immediate action:

1. The Minority Investigator Research Supplement initiative be extended to include all Institutes at the NIH and that those Institutes not currently making such awards develop plans and issue announcements so that Fiscal Year 1989 funding is available.

2. Administrative supplements to research grants also be made in order to provide opportunities to minority students for summer research experiences.

3. The National Research Service Award Short-Term Training Program be expanded to provide an opportunity for faculty at minority institutions to conduct research at major institutions for three to five months during the summer or during a school semester.

4. The NIH broaden the official announcement regarding the First Independent Research Support and Transition (FIRST) award to include language which specifically encourages minority scientists to submit such applications.

5. The NIH specifically encourage minority scientists at minority institutions to apply for the Academic Research Enhancement Award.

Options for consideration for development of long-range plans:

1. NIH officials should organize and conduct a series of hearings and group discussions in geographical regions close to Historically Black Colleges and Universities (HBCUs), and other predominantly minority institutions in which

concentrations of Hispanics and Native Americans are enrolled. Results of, and recommendations based on, these group discussions should be summarized and analyzed by a central NIH coordinating unit and submitted for action to the Director.

2. The NIH as a whole, as well as each Bureau, Institute, and Division, develop a comprehensive plan covering five to ten years in order to expand the national pool of underrepresented minority scientists doing biomedical research using regularly appropriated and set aside funds. These plans should be reviewed, modified, or expanded every two years, as the needs of scientific research and for research manpower are reassessed and the outcome of various programs is evaluated.

3. NIH develop a policy whereby health scientist administrators become more involved in the counseling and assisting of underrepresented minority scientists in regard to selecting appropriate funding mechanisms, developing research proposals, understanding the NIH peer-review system, and discussing proposed and ongoing research programs.

The Working Group anticipates that the combined impact of these recommended actions will facilitate the achievement of the national goal of substantial participation by minorities in the nation's biomedical enterprise, and that by expanding the pool of the nation's research scientists, the competitive position of the United States can be improved.

Report of The

Working Group on Minorities in Biomedical Research

National Institutes of Health

I. Introduction and Overview

At the regional meetings of the Advisory Committee to the Director, NIH, testimony was presented by concerned individuals and organizations regarding the underrepresentation of minorities in biomedical research. Although the National Institutes of Health (NIH) initiated efforts to address this problem in 1971, when several programs were developed (i.e., the Division of Research Resources' Minority Biomedical Research Support Program, and the National Institute of General Medical Sciences' Minority Access to Research Careers Program), it was pointed out by presenters that its efforts have to be increased. It is no longer sufficient just to increase opportunities, but rather, there must be an effort to specifically address the national problem of a declining scientific manpower pool and an increasing dependence on foreign students in some fields, (i.e., biochemistry). While the solutions are not simple, a number of good suggestions did emerge from the discussions at these regional meetings.

In order to assess the problem, some background statistics are necessary. Table 1 shows the racial or ethnic status of all United States citizens who earned the doctorate degree between 1975 and 1986. The conclusion is obvious: the number of Black scientists, while increasing slightly from 1975 to 1982, has actually declined over the past several years and the number of Hispanics in science has increased steadily but not very substantially. Appendix A provides further analysis of the statistics.

II. Programs of the National Institutes of Health

In addressing the problem of increasing the number of well-trained minority scientists in biomedical research, the NIH provides funds to minority institutions and individuals through a range of programs (Table 2) designed to provide research and research training opportunities, strengthen the overall undergraduate and graduate programs in such institutions, and attract and retain minority faculty members capable of serving as role models for the future generation of minority scientists. In Fiscal Year 1987, the National Institutes of Health provided approximately $69 million to minority institutions, and to minority investigators.

It should be emphasized that all the NIH research and research training programs are available to everyone. There are a large number of such programs, many with different foci and different goals, and minority scientists are encouraged to apply for support. Each of the Institutes tailors its own programs, which are open to everyone who meets the eligibility criteria, according to its legislated mission. Table 3 lists the variety of support mechanisms which all have, in common, the goals of increasing the numbers of scientists performing biomedical research and of research training with the ultimate goal of improving the health of the American people.

It is also of importance to note that, in March 1986, a decision was made by NIH that inclusion of minority students in research training grants is

critical in order to increase the manpower pool. A notice, thus, was published in the NIH Guide for Grants and Contracts concerning the need to actively recruit minority individuals into NIH National Research Service Award (NRSA) research training programs. This notice stated that, upon initial application and with each competing renewal, applications must include a description of the steps to be taken for the recruitment of individuals from underrepresented minority groups. Initial Review Groups are asked to comment on each applicant's plan for attracting minority individuals into productive research careers. This is then stated in an Administrative Note on the summary statement. The Advisory Councils are required to consider this information along with the assessment of the quality of research training and the overall scientific merit of the application. Such information is taken into account by the Institutes when funding decisions are made.

A. Programs Targeted to Minority Institutions

In the early 1970's, the National Institutes of Health developed programs to specifically increase the number of minority biomedical research scientists. With the support of the then Director, NIH and the Directors of all the Institutes, two initial activities were started:

- The Minority Access to Research Careers Program in the National Institute of General Medical Sciences, and
- The Minority Biomedical Research support Program (originally the Minority Biomedical Support Program)

These programs are outlined below and described in detail in Appendix B. It must be noted that a great expansion of effort has occurred since the 1970s as indicated by the participation of all of the Institutes at NIH in a large number of undertakings designed to engage the entire biomedical research community in improving the health of the nation. Such programs are also discussed in Appendix B.

1. Research Grant Programs

a) The two major NIH research grant programs which are targeted to minority researchers are The Minority Biomedical Research Support Program (MBRS), and The Research Centers in Minority Institutions (RCMI) Award.

i) The Minority Biomedical Research Support (MBRS) Program of the Division of Research Resources began in 1971 as an effort to attract faculty and students at minority institutions into biomedical research, to increase the biomedical research capabilities of such institutions, and to improve the faculty capabilities to conduct such research. Institutions participating are those which have historically drawn their students from minority populations, and those which, although historically considered to be majority institutions, now have large numbers of minority students and have shown a specific commitment to those students.

Most MBRS grants are awarded to two- and four-year colleges, universities, or health professional schools at which minorities comprise at least half of the enrollment. Grants also are awarded to institutions that have smaller, but still substantial, proportions of minority students if there is a demonstration of a special commitment to this segment of the student population.

ii) In Fiscal Year 1985, with a specific Congressional mandate, the NIH announced the establishment of The Research Centers in Minority Institutions Program (RCMI). This program is viewed as an institutional development award to enhance the infrastructure of those predominantly minority institutions that offer the doctorate in the health professions or the sciences related to health. The goal is to provide these institutions with the ability to conduct health-related research. The RCMI program was seen as a complementary effort to the programs of NIGMS and DRR that were already in existence. The program is designed to provide grants of up to $1 million (direct and indirect costs) per year for five years to assist eligible institutions in enriching their research environments by making selected improvements in both their human and physical resources. Funds awarded may be used for recruitment of faculty, the payment of salaries of key research and support personnel, expansion of departments, office support services, biostatistical support, programs in biosafety, purchase of state-of-the-art instrumentation, and alterations and renovation of facilities needed for the growth and improved functioning of an organization. Eligible institutions must have more than 50 percent minority student enrollment. In Fiscal Year 1987, the funding was $10 million.

b) In addition, in 1985, Congress called for an initiative to strengthen the research environment of those institutions of higher education which provide baccalaureate degrees for a significant number of our nation's research scientists, but which historically have not been major participants in the NIH grants programs. The Academic Research Enhancement Award (AREA) was thus established. In Fiscal Year 1988, an appropriation of just over $11 million was made for this initiative. These awards are for the support of new or expanded health-related research projects conducted by faculty in eligible institutions. The involvement of students on these projects is encouraged and seen as an opportunity to acquaint them with biomedical research careers. Although not specifically targeted to minority institutions, such institutions can compete for this award if they are eligible. Faculty at institutions in the United States that award baccalaureate and/or higher degrees in the sciences related to health are eligible, provided that the institution has not received an NIH Biomedical Research Support Grant of $20,000 or more per year for four out of the past seven years. Applicant-investigators may request support for up to $75,000 in direct costs for a period not to exceed 36 months. Although the AREA award is non-renewable, it does enable qualified individual scientists within these eligible institutions to receive support for feasibility studies, pilot projects

and other small-scale research endeavors preparatory to seeking more substantial funding through the regular NIH research grant programs. It is of interest that approximately 10 percent of these awards are to minority institutions eligible to participate in the Minority Access to Research Careers (MARC) institutions.

2. Research Training Grants Program

a) The National Institute of General Medical Sciences (NIGMS) has, as its mission, an emphasis on research training that undergirds the missions of the categorical NIH Institutes. These research training efforts are aimed at developing creative scientists capable of fundamental biomedical studies at the cellular and molecular level.

The NIGMS' Minority Access to Research Careers, started in 1972, aims to increase the number and capabilities of minority individuals engaged in biomedical research and teaching by funding research training at colleges and universities with substantial minority enrollment. The research training is provided to undergraduates, graduates, and faculty members in order to enhance the pool of minority biomedical researchers.

Details of the MARC Program and other NIH research training activities are given in Appendix B.

III. Federal Employment

Data regarding the status of Federally employed scientists are presented in Table 4. If the NIH, which plays a key role as a performer of important research and development in biomedicine and its related fields, is to help bring more underrepresented minorities into biomedical research, its own work force should reflect that effort. Data that were gathered for presentation to the President's Task Force on Women, Minorities, and the Handicapped are presented in Tables 5 and 6. This Task Force was established in 1987 by Public Law 99-383, Section 8. Its purpose is to examine the current employment status of women, minorities, and the handicapped in science and engineering positions in the Federal Government and in federally assisted research programs. It is the position of the Task Force that to put Federal agencies at the leading edge of developing a truly diverse work force, goals for hiring and promotion should be a part of each Agency's 10-year plan for addressing this issue.

In the Federal work force:

- Employment in the Biological Sciences Series represents the largest number of minority researchers, followed by the Physical Sciences Series, and then the Social and Behavioral Sciences Series.

- Numerically, NIH employs the greatest number of minority researchers (333 of 2393), which represents 13.9% of the NIH work force.

- FDA employs the greatest percentage (19.6%) of minority researchers.

- For the 4 Public Health Service (PHS) Agencies, ADAMHA, FDA, HRSA, NIH, there are 473 minority researchers out of a total of 3,272 research employees.

IV. Minority Scientists Holding NIH Research and Research Training Grants

There are no firm data available as to the numbers of research grant and development dollars awarded to minority scientists by the NIH or by the Public Health Service as a whole. Table 7 presents the data for Fiscal Year 1987 as gathered for the Report of The President's Task Force on Women, Minorities and the Handicapped. Since the reporting of such information is entirely optional and many investigators choose not to complete that particular section of a grant application, it is not possible to draw conclusions as to how members of minority groups fare in the Federal research and development system.

While there is a history of specific Federal support for minority institutions, primarily the Historically Black Colleges and Universities, it has existed at a modest level for several decades. Increased support to these 101 academic institutions from various Federal agencies has been provided since the issuance of Executive Order 12320 by President Reagan in September 1981. This Order mandated Federal programs "to advance the development of human potential, to strengthen the capacity of Historically Black Colleges and Universities, to provide quality education, and to overcome the effects of discriminatory treatment." Most Federal scientific agencies have "set-aside" programs which provide institutional support to these institutions. The Minority Access to Research Careers and the Minority Biomedical Research Support programs of the NIH, described above, are convincing examples of successful Federal efforts to develop minority institutions and of programs targeted to individuals in minority groups who can make important contributions to the progress of biomedical research.

V. Summary of Testimony

Although speakers at the regional meetings generally expressed appreciation for the efforts made by the NIH, and the role it has played in providing research and training opportunities at minority institutions, the feeling was that there is still much to be done. The MBRS and the MARC programs were singled out as government programs in which success can actually be observed. The MBRS program of DRR has provided research opportunities in undergraduate science careers to minority students, and assured and provided encouragement for opportunities comparable to those of non-minority students to pursue science careers. The MBRS program and the DRR high school minority research apprentice activity were called "demonstrated successes" and deserving of enthusiastic continuing support.

The NIGMS MARC Program was specifically noted as a program that provides meaningful research experiences for a group of highly qualified minority students. There was praise from a MARC predoctoral trainee who stated that, without this program, she and others like her (honor students from Puerto Rico) would not have had the opportunity to complete their careers as scientists and would not be contributing to scientific progress today. Pleas were made for funds to be made available to increase the number of MARC Honors Undergraduate Research Training Programs, and for an increase in the number of trainees.

In order to provide a perspective, however, it was noted that majority institutions receive funding from NIH which is two and one-half to three times greater than the average minority institution. Many of the above described NIH programs are thus designed to alter this discrepancy.

One speaker read a statement from representatives of the Historically Black Colleges and Universities offering NIH their wholehearted support and applauding its programs and efforts to ensure that the biomedical research community is broadly based. NIH was praised for recognizing that minority institutions serve as an ample source of talented students and developing programs to attract these students into biomedical science careers. Other programs that were mentioned as being particularly helpful to the minority community were the NHLBI's hypertension training centers, regular research grant supplements by NHLBI, NCI, NIDR and NIAID, and faculty development awards.

It was emphasized that, if the pool of scientific manpower is not to dry up, long-range plans must be put into place now. It was felt that NIH must realistically appraise what is necessary in order to bring a few minority institutions up to a point where they are competitive with majority institutions. If this is not done, the minority scientist will never have his or her rightful place in society. NIH has been imaginative in setting up programs to bring more minorities into research but certain improvements should be made:

1) seed funds are needed,

2) sustaining funds are needed, and

3) the needs of minority scientists outside the programs under the "affirmative action umbrella" should be considered in future plans for research funding.

Finally, it was stated that Federal agencies can help both minority and non-minority institutions by devoting more attention to funding the research of scientists during the first years of their careers.

VI. Options

The Working Group has prepared two sets of options. One set proposes specific actions that can be taken immediately, and the other, the development of long-range plans.

A. Options for consideration for immediate action:

1. The Minority Investigator Research Supplement initiative be extended to include all Institutes at the NIH and that those Institutes not currently making such awards develop plans and issue announcements so that Fiscal Year 1989 funding is available. Currently, there are four Institutes (NCI, NIAID, NIDR, and NHLBI) that have announced and are supporting this program encompassing the following:

   - These administrative supplements to existing research or program project grants are for biomedical research support of underrepresented minority investigators that are junior faculty members or clinical residents at either a majority or minority college, university or health professional school.

- Any principal investigator with an active research grant that has a minimum of two years of research support remaining is eligible to submit a request for such a supplement to a minority investigator.

- These awards should be for a minimum of two years and should be limited to salary, supplies, and travel for the minority investigator. The allowable maximum for these awards should be no more than $50,000 in direct costs.

- The research project in which the minority investigator will participate must be a part of the parent grant that has been previously approved and awarded. No technical merit review will be required before such a supplementary award is made.

The availability of these supplemental awards was first announced three years ago making any evaluation or assessment premature at this time. However, they do appear promising, and this effort represents the first attempt to assist in the development of biomedical research careers of underrepresented minority individuals who may not be at minority institutions.

2. Administrative supplements to research grants also be made in order to provide opportunities to minority students for summer research experiences.

   - The objective of this program is to reach out to the pool of students from minority groups currently underrepresented in biomedical sciences and give them an opportunity to develop an interest in biomedical research.

   - Funds under this initiative would be made available to research grant recipients to bring minority undergraduate students to spend the summer doing research and hopefully motivate them to pursue biomedical research careers. The recommended items for support are: (1) salary enabling the student to live away from home, (2) travel to and from home to site of laboratory, and (3) minimal supplies needed for student participation.

   - A number of procedures should be used to couple investigators holding research grants to appropriate minority students. These include:

     - Investigator initiated -- the Principal Investigator identifies the student and initiates the request for a supplement.

     - The institution makes the pairing and requests the supplement.

     - The student contacts NIH, the grantee institution or the investigator and requests a summer research experience. The supplement is then submitted by the grantee institution.

°° NIH provides student names to investigators and investigators' names to students based on inquiries, and on student support by NIH programs such as MARC and MBRS.

3. The National Research Service Award Short-Term Training Program be expanded to provide an opportunity for minority faculty to conduct research for three to five months during the summer or during a school semester.

° As noted earlier, teaching is the primary activity of under-represented minority faculty and few are engaged in research because of heavy teaching obligations. A short-term training program which emphasized research would be one way to encourage more minority researchers to retain, update, and enhance their research capabilities during times which are convenient for them to do so.

4. The NIH broaden the official announcement regarding the First Independent Research Support and Transition (FIRST) award to include language which specifically encourages minority scientists to submit such applications.

5. The NIH specifically encourage minority scientists at minority institutions to apply for the Academic Research Enhancement Award.

B. Options for consideration for long-range plans:

1. NIH officials should organize and conduct a series of hearings and group discussions in geographical regions close to Historically Black Colleges and Universities, and other predominantly minority institutions in which concentrations of Hispanics and Native Americans are enrolled. Results of, and recommendations based on, these group discussions should be summarized and analyzed by a central NIH coordinating unit and submitted for action to the Director.

° These hearings would provide opportunities for science faculty and administrators as well as science students to offer descriptions and models of programs that they believe should be developed, continued, or revised at their institutions with NIH support and in collaboration with other organizations.

° These discussions should focus on: 1) the improvement of the quality of science and biomedical research at the minority institutions and 2) the expansion of the pool of minority students who may become biomedical science researchers. Additionally, it would be desirable to encourage these institutions to broaden their research capabilities where possible.

° Invited participants should be reimbursed by NIH for travel and lodging expenses so that there are as few barriers to participation as possible.

° In planning such hearings, there should be an effort to listen to the faculty of HBCUs which do not emphasize the development of future research scientists even though they offer basic science

curricula. Given the fact that a vast majority of Blacks begin their college education at HBCUs, faculty at these schools may have much to say about the numbers of students in the talent pool who ultimately become biomedical researchers, the quality of research training that those students are offered, and how to improve the confounding issue of providing opportunities for the underserved student who often comes to college with deficient or little preparation in science.

2. The NIH as a whole, as well as each Bureau, Institute, and Division, develop a comprehensive plan covering five to ten years to expand the national pool of underrepresented minority scientists doing biomedical research using regularly appropriated and set-aside funds. These plans should be reviewed, modified, or expanded every two years, as the needs of scientific research and for research manpower are reassessed and the outcome of various programs is evaluated.

3. NIH develop a policy whereby health scientist administrators become more involved in the counseling and assisting of underrepresented minority scientists in regard to selecting appropriate funding mechanisms, developing research proposals, understanding the NIH peer-review system, and discussing proposed and ongoing research programs.

   ° Developing new mechanisms to achieve a desired goal is only part of the solution to increasing the number of underrepresented minority scientists. In order for scientists to fully utilize these opportunities, the programs and the system of application, review, and selection must be fully understood by prospective applicants. This information can be disseminated accurately only by Institute been major participants in NIH programs, NIH officials should be aware of the need to develop outreach programs targeted to the needs of minority institutions and their scientists.

The Working Group anticipates that the combined impact of these recommended actions will facilitate the achievement of the national goal of substantial participation by minorities in the nation's biomedical enterprise, and that by expanding the pool of the nation's research scientists, the competitive position of the United States can be improved.

Race/Ethnic Status of Ph.D.s: U.S. Citizens*, 1975-86

Year of Doctorate	Numbers of Ph.D.s			
	Black	Hispanic	Asian-American	White
1975	999	303	286	24,352
1976	1,095	340	344	24,373
1977	1,116	423	339	23,065
1978	1,033	473	390	21,811
1979	1,056	462	428	21,920
1980	1,032	412	458	21,993
1981	1,013	464	465	21,979
1982	1,047	535	452	21,674
1983	921	538	492	21,673
1984	953	535	512	21,321
1985	909	559	515	20,641
1986	820	567	527	20,538
	Percent of Ph.D.s			
1975	3.8	1.2	1.1	93.7
1976	4.2	1.3	1.3	93.1
1977	4.5	1.7	1.4	92.2
1978	4.3	2.0	1.6	91.8
1979	4.4	1.9	1.8	91.5
1980	4.3	1.7	1.9	91.8
1981	4.2	1.9	1.9	91.6
1982	4.4	2.2	1.9	91.1
1983	3.9	2.3	2.1	91.4
1984	4.1	2.3	2.2	91.1
1985	4.0	2.5	2.3	90.9
1986	3.6	2.5	2.3	89.4

*Excludes other races and no-report cases of doctorate recipients reporting race/ethnic status.

Source: National Research Council, Office of Scientific and Engineering Personnel, Survey of Earned Doctorates, 1975-1986.

Table 1

TABLE 2

NIH TOTAL FUNDING FOR MAJOR MINORITY-TARGETED PROGRAMS

(1973-1988)

Year	Total NIH Budget (Thousands)	MBRS (Thousands)	MARC (Thousands)	RCMI (Thousands)	Total Expenditure for Minority Activities (Thousands)	Percent of NIH
73	1,762,565	5,000	0	0	5,000	0.284%
75	2,092,897	7,300	0	0	7,642	0.365%
77	2,544,078	9,711	1,788	0	13,572	0.533%
79	3,184,976	14,584	2,870	0	22,159	0.696%
81	3,569,406	18,857	4,515	0	29,518	0.827%
83	4,023,969	19,800	5,975	0	32,495	0.808%
85	5,144,650	24,951	7,741	5,000	47,902	0.931%
87	6,180,660	28,268	8,566	10,000	56,377	0.912%
88	6,666,993	28,520	8,945	11,010	58,327	0.875%

Table 3

OTHER NIH PROGRAMS

°NIH Staff Fellowships

°NIH Medical Staff Fellowship Program

°National Research Service Awards for Institutional Training: Short-Term Training for Students in Health Professional Schools (T35) Institutional Training Grants (T32)

°National Research Service Awards: Individual Predoctoral Fellowship (F31), Individual Postdoctoral Fellowship (F32), Senior Fellowship (F33)

°Senior International Fellowships (F06)

°Small Grants Program (R03)

°Clinical Investigator Award (K08)

°Physician Scientist Awards (K11, K12)

°Research Career Development Award (K04)

°Small Business Innovation Research Program, Phase I (R43)

°First Independent Research Support and Transition (FIRST) Award (R29)

°Research Project Grants (Traditional) (R01)

Federal Scientists and Engineers, 1977/1987

	1977		1987	
	#	%	#	%
Total	202,808	100.0	254,978	100.0
Women	15,283	7.5	41,210	16.2
Black	7,412	3.7	13,410	5.3
Hispanic	2,523	1.2	6,742	2.6
Asian	3,604	1.8	11,830	4.6
Native American	595	0.2	1,455	6.6
White	184,843	91.1	220,435	86.7
Unspecified	3,831	1.9	206	0.8
Disabled	12,830	6.3	12,213	4.8

Table 4

Source: Draft Interim Report, Task Force on Women, Minorities and the Handicapped in Science and Technology, April 1988.

Table 5

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
Task Force on Women, Minorities, and the Handicapped in Science & Technology

NUMBER OF EMPLOYEES BY AGENCY, MINORITY/NON-MINORITY and RESEARCH CATEGORY

AGENCY	Biological 1/ Sciences	Physical 2/ Sciences	Soc. & Behav. 3/ Sciences	Total 4/ 1+2+3	Staff 5/ Fellows	Total 4+5
ADAMHA						
Minority	9	8	3	20	14	34
Non-Minority	96	29	56	181	115	296
Total	105	37	59	201	129	330
FDA						
Minority	37	47	1	85	18	103
Non-Minority	200	141	5	346	77	423
Total	237	188	6	431	95	526
HRSA						
Minority	2	0	1	3	0	3
Non-Minority	16	4	0	20	0	20
Total	18	4	1	23	0	23
NIH						
Minority	139	90	2	231	102	333
Non-Minority	912	475	30	1417	643	2060
Total	1051	565	32	1648	745	2393
ALL AGENCIES						
MINORITY	187	145	7	339	134	473
NON-MINORITY	1224	649	91	1964	835	2799
TOTAL	1411	794	98	2303	969	3272

1/ General Biological Sciences, Genetics, Microbiology, Pharmacology, Physiology, Medical Officer, Statistician, Entomology, Mathematical Statistician
2/ Chemistry, Physics, Biomedical Engineering, Mathematics
3/ Social Science, Sociology, Psychology, Anthropology
4/ Total Series (1+2+3)/Population = GS, GM ES, HHGE, CC, AD/Functional-code EQ "11" + "13"
5/ FIT (excluding visiting scientists)
1/5/88

Table 6

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
Task Force on Women, Minorities, and the Handicapped in Science & Technology

PERCENTAGE OF EMPLOYEES BY AGENCY, MINORITY/NON-MINORITY and RESEARCH CATEGORY

AGENCY	Biological 1/ Sciences	Physical 2/ Sciences	Soc. & Behav. 3/ Sciences	Total 4/ 1+2+3	Staff 5/ Fellows	Total 4+5
ADAMHA						
Minority	8.6	21.6	5.1	10.0	10.9	10.3
Non-Minority	91.4	78.4	94.9	90.0	89.1	89.7
Total	100.0	100.0	100.0	100.0	100.0	100.0
FDA						
Minority	15.6	25.0	16.7	19.7	18.9	19.6
Non-Minority	84.4	75.0	83.3	80.3	81.1	80.4
Total	100.0	100.0	100.0	100.0	100.0	100.0
HRSA						
Minority	11.1	0.0	100.0	13.0	*	13.0
Non-Minority	88.9	100.0	0.0	87.0	*	87.0
Total	100.0	100.0	100.0	100.0	*	100.0
NIH						
Minority	13.2	15.9	6.3	14.0	13.7	13.9
Non-Minority	86.8	84.1	93.8	86.0	86.3	86.1
Total	100.0	100.0	100.0	100.0	100.0	100.0
ALL AGENCIES						
MINORITY	13.3	18.3	7.1	14.7	13.8	14.5
NON-MINORITY	86.7	81.7	92.9	85.3	86.2	85.5
TOTAL	100.0	100.0	100.0	100.0	100.0	100.0

1/ General Biological Sciences, Genetics, Microbiology, Pharmacology, Physiology, Medical Officer, Statistician, Entomology, Mathematical Statistician
2/ Chemistry, Physics, Biomedical Engineering, Mathematics
3/ Social Science, Sociology, Psychology, Anthropology
4/ Total Series (1+2+3)/Population = GS, GM ES, WAGE, CC, AD/Functional-code EU "11" + "13"
5/ FIT (excluding visiting scientists)
1/5/88

Table 7

Department of Health and Human Services

Investigators Holding Research Grants

	NIH	CDC
	No.	No.
Women *	2426	6
Minorities *	1455	2
Handicapped	N.A.+	N.A.+
Unknown	5633	17
TOTAL GRANTEES	19,902	56
	ADAMHA	NCHSR
	No.	No.
Women *	313	17
Minorities *	92	1
Handicapped	N.A.+	N.A.+
Unknown	547	21
TOTAL GRANTEES	1844	67

+ Not Available

* These data are not accurate since reporting is optional. This, at best, constitutes an estimate.

Appendix A

Overview of Statistics

A 1986 National Academy of Sciences/National Research Council's Summary Report: Doctorate Recipients from United States Universities provides an important overall discussion of this issue:

> "The racial composition of new Ph.D. cohorts also changed between 1977 and 1986. Table E displays the number of doctorate recipients by sex, racial/ethnic group, and citizenship status, 1977-1986. The smallest group getting Ph.D.s has consistently been American Indians; the largest has consistently been whites. In between, the order from low to high was: Hispanic, black, Asian. While the sequence of these groups has remained the same, their sizes have changed. Hispanics and, especially, Asians have increased their shares of doctorates earned; blacks and whites have decreased their shares. The groups also display differences in their field distributions, and Table F shows those differences for U.S.-citizen doctorate recipients in 1986.
>
> The decline in numbers of black and white Ph.D.s occurred primarily within the U.S.-citizen stratum. The most significant decline was among U.S. blacks. The number of black American doctorates dropped from 1,116 to 820, a reduction of 26.5 percent, which was not evenly distributed between the sexes. The number of Ph.D.s awarded to U.S. black males decreased by more than half, whereas the number of Ph.D.s awarded to U.S. black women rose 15.5 percent. As evidenced in Table F, American blacks of both sexes tended to cluster in the field of education.
>
> In addition, the number of white American doctorates declined. Their 11 percent reduction was also a result of losses among male recipients, which were only partially offset by increases on the part of white women.
>
> On the other hand, important gains were made by other groups. Chief among them were Asians, especially those on temporary visas. In 1977, Asians earned 6.9 percent of the doctorates, and by 1986 they earned 12.8 percent. Also, by 1986 Asians had become the largest racial group (54.7 percent) of temporary-resident doctorates; whites had been the biggest group in 1977. In addition, Asian Americans also increased their participant share, from 1.4 percent of U.S.-citizen doctorates in 1977 to 2.3 percent in 1986. Table F shows that Asian Americans were largely concentrated in the life sciences.
>
> The number of Hispanic Ph.D.s also increased in every citizenship stratum, especially among the temporary-visa group. Hispanics earned 2.4 percent of the doctorates in

> 1977 and 3.6 percent in 1986. Much of the growth among the U.S. Hispanic group was attributable to a rise in the number of women doctorates: by 1986, U.S. Hispanic women were at near parity with their male counterparts (47.3 percent). Like U.S. blacks, U.S. Hispanics tended to cluster in the education field.
>
> Finally, the numbers and proportions of American Indians went up over the decade, peaking at 100 in 1986 (virtually all are U.S. citizens, although occasionally cohorts will include Canadian and Latin American Indians). Because their numbers have always been quite low, even small variations can change the picture quite dramatically. For example, in 1985, 58.1 percent of American Indian recipients were women, but in 1986 the balance shifted, and 59 percent were men. Despite the irregular trend, it does appear that the number of American Indians receiving doctorates is gradually increasing (0.2 percent in 1977; 0.3 percent in 1986)."

A further report 1/ has been given on the state of American higher education and of the college and university faculty members who are so critical to the development, change, and progress of such education. In general, faculty at institutions of higher learning has been characterized as a "national resource imperiled"; moreover, there is increasing evidence that faculty members from underrepresented minority groups face an uncertain future on U.S. college and university campuses. While it is clear that the nation's minority college and university professoriate occupies an important role in contemporary higher education, and that institutions of higher learning have made some progress in increasing such participation in traditionally white faculties, in recent years, the rate of this progress has waned and even been reversed for faculty members who are Black.

The need for more faculty members from underrepresented minority groups is clear. Despite the enactment of affirmative action programs in the 1960s, full-time Black faculty positions decreased from 19,674 to 18,827 between 1977-1983, and the decline has been in both public (-6.2 percent) and private (-11.3 percent) four-year institutions. Moreover, in 1983, representation of full-time Black faculty in traditionally white institutions was only 2.3 percent, and the 1986 report of the American Council on Education regarding their status shows that their participation is declining in most states.

During the same time period, full-time Hispanic and Asian-American faculty members have made progress, but at different rates. The former increased at the rate of 26 percent, from 6,505 to 8,311; the latter, by 38 percent, from 11,917 to 16,398. Thus, experiences have been varied among minority faculty in academia, with Black professionals losing ground.

1/ Source: Increasing Minority Faculty: An Elusive Goal, (A Minority Graduate Education Project sponsored by the GRE Board and the ETS), Shirley Vining Brown

In 1986, Blacks accounted for 2.5 percent of all employed scientists and engineers. Although this proportion was up from 1.6 percent in 1976, it was still lower than their proportion in other fields. Blacks accounted for 10 percent of total U.S. employment in 1986 and almost 7 percent of all employed professional workers and those in related fields.

The representation of Native Americans is about the same among scientists and engineers as in the overall U.S. work force (less than 1 percent). Data regarding Native Americans, however, should be viewed with caution since they are based on an individual's perception of his or her Native American heritage; such perceptions may change over time. Additionally, sample sizes for native Americans are small and statistical reliability is thus less certain regarding this racial group.

Other important statistics follow: In 1986, Hispanics represented 2 percent of all employed scientists and engineers; this was down from 2.2 percent in 1984. For the same year, roughly 7 percent of all employed persons and more than 3 percent of those in professional fields were Hispanic.

Approximately 30 percent of employed Hispanic scientists and engineers were Mexican American; 15 percent were Puerto Rican. The remaining 55 percent were either "other Hispanic" or did not report their specific Hispanic origins.

Overall, minority underrepresentation in academia has been attributed to three factors. First, among Asian-Americans and Hispanics, it is associated with the slowdown in doctoral production. However, within the Black community, this is related to a real and relative decline in the doctorate pool. Second, among new minority Ph.D.s, the proportion choosing careers in academia is dwindling. Third, there is a lack of retention of minority faculty by academic institutions. Thus, the problems of underrepresentation are supply, flow into and through the academic pipeline, and retention. The major findings of the 1986 Academy report on minority doctorates are summarized below.

1) Minority Ph.D.s in the Labor Force

Almost all minority Ph.D.s were fully employed in 1985, and the majority were employed full-time in four-year institutions. However, there was a notable shift in the plans of such faculty members toward nonacademic employment between 1975 and 1986.

The shifting of fields by minorities in science and engineering varied by race and ethnic group and by discipline. Retention rates (i.e., those doctorates who remained in the field in which the Ph.D. was awarded) were highest for those in the computer sciences. In the humanities, the field of music had the highest retention rate, although Black professionals in art history, and English/American language and literature, and Hispanics in speech and theater also tended to stay in their fields. The change in field was highest in the "other" humanities.

Compared to earlier cohorts, individuals with Ph.D.s earned in 1985 were more likely to take jobs outside of their doctorate field, citing two primary reasons for doing so: (1) more attractive career options in other areas, and (2) the inability to find jobs in their field. Black and Hispanic professionals were more likely than were Asian-Americans to

report that they were attracted to jobs outside of their doctoral field because of better salaries.

2) Minorities in Academia

Between 1975 and 1985, there were continued increases in appointments of minority Ph.D.s to full-time faculty positions. With the exception of Asian-Americans, most were in departments of social sciences and humanities. Asian-Americans were as likely to be employed in the life sciences as in the social sciences.

The median salaries for minority faculty members were substantially lower than those of comparable minority Ph.D.s in business and private industry. In academia, however, Black faculty members generally earned higher salaries than members of other minority groups, except in engineering, where Asian-Americans had the highest earnings. In the nonacademic sector, Black professionals earned lower salaries than did other comparable groups.

Teaching was the primary activity of Black and Hispanic faculty members; they also more frequently reported being involved in administration than did other minority faculty. Compared to Asian-Americans and Hispanics, few Black faculty members were engaged in research. In contrast, Asian-Americans were most likely to report research as a primary activity, and least likely to be in administration.

A number of longitudinal studies have shown that Black Ph.D.s had the lowest promotion and tenure rates among minority faculty members, and were consistently below the national average. Asian-Americans had the highest promotion and tenure rates, and both Asian-American and Hispanic faculty had promotion and tenure rates above the national average. The results of these analyses were not displayed by academic field, however.

TABLE E: Doctorate Recipients, by Sex, Race, and Citizenship, 1977–1986 (Appendix A)

Race/Ethnicity	Year of Doctorate									
	1977	1978	1979	1980	1981	1982	1983	1984	1985	1986
MEN										
American Indian										
U.S.	43	50	56	46	56	44	50	53	39	58
Permanent Visas*	–	–	–	–	–	–	1	–	–	–
Temporary Visas*	4	1	3	–	–	–	–	–	–	1
Asian										
U.S.	251	287	311	313	315	281	312	338	329	347
Permanent Visas	488	531	564	513	499	444	431	389	437	412
Temporary Visas	955	1,114	1,253	1,282	1,341	1,567	1,731	1,982	2,137	2,252
Black										
U.S.	684	584	551	499	499	483	412	427	379	321
Permanent Visas	70	65	52	63	80	81	73	81	117	106
Temporary Visas	236	252	288	305	339	340	339	382	354	275
Hispanic										
U.S.	310	317	308	256	275	344	288	313	300	299
Permanent Visas	36	52	52	48	47	52	45	47	50	71
Temporary Visas	210	251	310	280	321	247	288	252	294	288
White										
U.S.	17,011	15,573	15,261	14,848	14,458	13,984	13,599	13,155	12,778	12,257
Permanent Visas	446	379	319	326	331	309	381	350	367	409
Temporary Visas	1,252	1,197	1,068	1,129	1,225	1,242	1,287	1,223	1,272	1,214
WOMEN										
American Indian										
U.S.	22	10	25	29	29	33	30	20	56	41
Permanent Visas*	1	–	–	–	–	–	–	–	–	–
Temporary Visas*	–	–	–	–	–	–	–	–	–	–
Asian										
U.S.	88	103	117	145	150	171	180	174	187	180
Permanent Visas	83	111	110	131	109	108	120	118	116	111
Temporary Visas	163	197	210	190	223	262	275	313	389	387
Black										
U.S.	432	449	505	533	514	564	509	526	533	499
Permanent Visas	8	8	6	11	17	15	10	21	14	20
Temporary Visas	13	18	32	26	33	33	24	37	41	38
Hispanic										
U.S.	113	156	154	156	189	191	250	222	261	268
Permanent Visas	15	13	25	25	15	27	24	24	23	36
Temporary Visas	22	38	38	48	68	47	54	48	67	83
White										
U.S.	6,054	6,238	6,659	7,145	7,521	7,689	8,074	8,168	7,926	8,281
Permanent Visas	143	152	157	142	159	154	163	163	167	183
Temporary Visas	196	175	195	201	207	216	252	267	295	290

* In most cases, non–U.S. American Indians are citizens of Canada or of Latin American countries.

Source: 1986 NAS/NRC Summary Report: Doctorate Recipients from United States Universities

TABLE F: Race/Ethnicity, Sex, and Field of Degree of 1986 Doctorate Recipients (U.S. Citizens)

Race/Ethnicity	Field of Doctorate							
	Total Fields	Physical Science	Engi-neering	Life Sciences	Social Sciences	Humanities	Education	Professional and Other
U.S. Citizens								
Total	22,984	3,003	1,379	4,342	4,548	2,728	5,595	1,389
Men	13,583	2,486	1,240	2,733	2,414	1,477	2,403	830
Women	9,401	517	139	1,609	2,134	1,251	3,192	559
American Indian								
Total	99	8	6	23	20	7	26	9
Men	58	4	5	11	12	6	16	4
Women	41	4	1	12	8	1	10	5
Asian								
Total	527	107	80	152	69	30	58	31
Men	347	84	74	92	40	10	25	22
Women	180	23	6	60	29	20	33	9
Black								
Total	820	25	14	64	163	70	421	63
Men	321	18	10	28	70	28	141	26
Women	499	7	4	36	93	42	280	37
Hispanic								
Total	567	53	25	72	130	76	188	23
Men	299	41	22	39	75	38	68	16
Women	268	12	3	33	55	38	120	7
White								
Total	20,538	2,714	1,224	3,958	4,080	2,496	4,820	1,246
Men	12,257	2,253	1,102	2,507	2,164	1,366	2,114	751
Women	8,281	461	122	1,451	1,916	1,130	2,706	495

Appendix B

Programs Targeted to Minority Institutions

A. Research Grants Activities

1. The Minority Biomedical Research Support Program (MBRS) of the Division of Research Resources has goals that have been carried out through three subprograms: the Regular MBRS Program Project Grants, the Undergraduate College Research Participation Award, and the Thematic Grant Awards. Two other funding mechanism are also employed: the Supplemental Award for Shared Instruments and a provision for supporting minority students participating in research directed by investigators at an institution having a minority enrollment of less than 50 percent.

   Most institutions receive regular MBRS Program Project Grants, the oldest of the MBRS subprograms. Funds support a program administrator at each institution and groups of individual research projects. Participating in these projects are student research assistants. The award allows faculty members, who frequently have prohibitively heavy teaching loads, to devote more of their time to research and to the development of research skills as the students conduct research. Moreover, students are given "hands on" experience in actual laboratory studies.

   Begun in 1985, the Undergraduate College Research Participation Awards subprogram seeks to enhance research capabilities at two and four-year colleges which are primarily oriented toward minority students but which, for a variety of reasons, have not been successful in securing the resources necessary to support scientific research. The awards, which are limited to $150,000 per year in direct costs, support enrichment activities, pilot research projects, as well as regular research projects. Enrichment activities encompass items such as travel to scientific meetings, seminars, workshops, and participation by faculty and students in research at off-campus laboratories during the summer. This program is ongoing and currently involves 12 institutions. The Division of Research Resources plans an expansion of this subprogram in future years.

   The Thematic Grant Awards were established to support minority institutions that grant doctoral degrees. The intent was that institutions with a minority student population of at least 50 percent and a demonstrated level of research expertise would be eligible for this award. MBRS Thematic Awards, limited to $300,000 per year in direct costs, were made to three institutions in Fiscal Year 1985 and to one additional institution in Fiscal Year 1986. The awards were intended to stimulate multidisciplinary or interdepartmental collaboration within a particular biomedical research theme at institutions having appropriate facilities and postdoctoral staff. This program has been temporarily discontinued.

   Supplemental Awards for Shared Instruments allow qualifying institutions (those receiving MBRS funding) to obtain equipment that normally would exceed that allowed for a single research project, and

is essential to the success of several projects. These grants range from $25,000 to $150,000. Examples of the instrumentation obtained include cell sorters, nuclear magnetic resonance spectrometers, and high performance liquid chromatography systems. Eleven awards were made in Fiscal Year 1987. This program was also discontinued temporarily in 1988.

The MBRS Program also provides support to institutions having a minority enrollment of less than 50 percent for minority graduate and undergraduate students engaged in research projects directed by investigators having their own research support.

Other sponsors of biomedical research, including most awarding units within the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) have collaborative agreements with the MBRS Program to co-fund certain projects at MBRS institutions. MBRS staff monitor such projects which pertain to the missions of the sponsoring NIH or ADAMHA Agency. In 1987, co-funding arrangements provided support for 232 projects and totaled nearly $11 million. In contrast, in 1975, when the co-funding arrangements were started, only nine projects received this type of support. (Table 1)

2. The categorical Institutes at NIH offer a variety of programs targeted toward stimulating interest of minorities in research opportunities as they relate to their specific missions and programs. In addition, they all contribute to the MBRS and MARC program activities. Following is a summary of the programs that were available in Fiscal Year 1987 to attract minorities into biomedical research careers.

   i) The National Institute of Allergy and Infectious Diseases' (NIAID) Minority Research Enhancement Program provides support for underrepresented minority researchers through supplemental grants to institutions having active previously peer-reviewed NIAID grants. These may include, but are not limited to, regular research project (R01) and program project (P01) grants. This supplement to an NIAID-researcher is for the purpose of: (1) increasing the number of underrepresented minority personnel on the grant actively pursuing research objectives relevant to the mission of the Institute, and (2) strengthening funded projects by enlarging the pool of scientific talent. The NIAID also has a formal program, "Introduction to Biomedical Research," an annual affirmative action initiative designed to inform academically talented students from underrepresented minority groups of career opportunities in biomedical research, particularly within its intramural program.

   ii) The National Cancer Institute (NCI) offers (1) the Minority Investigator Supplement, a special initiative which provides supplemental funds to NCI grantees who apply for support of minority researchers to participate in their projects, and (2) a Travel Award for Young Investigators -- a special initiative providing travel funds to minority students and faculty researchers to attend the annual meeting of the American Association for Cancer Research.

The first Minority Consortium Cancer Center Planning Grants were funded by NCI during Fiscal Year 1986. These three-year grants are expected to enable the three institutions involved (Charles R. Drew Medical Center, Meharry Medical College, and Morehouse School of Medicine) to strengthen their research infrastructure, thus resulting in the acquisition of a significantly increased grant support base as well as an enhanced capability to do research in cancer control.

NCI recently announced a Centers Minority Enhancement Award. This request for applications is for a single competition with a deadline of August 2, 1988. The announcement invites applications for supplemental support to Cancer Center grants which have access to large minority populations in order to expand the involvement of minority scientists in cancer research. These Cancer Centers will promote the participation of minority groups in research by broadening their operational base to facilitate the expansion of cancer control efforts in early detection, prevention, screening, pre-treatment evaluation, treatment, and continuation care and rehabilitation. The increased involvement of primary care providers for minority populations early in the course of clinical treatment is also a goal.

The Minority Satelite Supplement enables the NCI's Clinical Cooperative Groups to increase accrual of minority patients into clinical trials. This initiative also promotes increased participation by minority physicians in research as well as in education for cancer prevention.

iii) The National Institute of Child Health and Human Development (NICHD) supports research at three of the Historically Black Colleges -- Meharry Medical College, Morehouse School of Medicine and Howard University -- and makes long-term loans of scientific equipment to minority colleges. In addition, there are frequent and active staff interactions with faculty and students at Black colleges via lecture series, consultant work, etc.

iv) The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) offers selective affirmative action initiatives aimed at improving the representation of minorities, women, and the handicapped in the neurosciences. These include travel grants to the Society for Neuroscience for academically talented students and junior scientists, especially minorities, to attend its annual meeting, and sponsorship of workshops on research training opportunities in the neurosciences in conjunction with a number of professional scientific societies. In addition, the NINCDS Outreach Program, in existence since 1978, conducts seminars and workshops at academic institutions and at scientific meetings to enable students, predoctoral and postdoctoral candidates, and clinical residents to become familiar with the NINCDS intramural research training programs as well as the NINCDS extramural research and research training programs. The Outreach Program also strives to develop a network of resources in the scientific community that will identify potential candidates for research

training positions at the NINCDS. As a result of these outreach activities, there has been a substantial improvement in the size of the applicant pool of minorities and women competing for positions in the Summer Research Fellowship Program and the NINCDS Summer Program in the Neurosciences, and to some extent in the NINCDS intramural postdoctoral research program.

v) The National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK) offers the Minority Investigator Research Enhancement Award (MIREA). These awards provide support for faculty members of minority institutions to allow them to collaborate with principal investigators of active regular research grants funded by NIDDK. NIDDK also provides support for minority students and faculty members of minority institutions involved in biomedical research to allow them to attend national scientific meetings through its new Minority Travel Award Program (MTAP). The overall purpose of this program is to strengthen biomedical research and training in institutions with significant commitments to minorities and to increase awareness and participation of minority scientists in biomedical research. The NIDDK Summer Research Training Program for Undergraduate Minority Students, which began in 1985, is a 10-week research experience for undergraduate students who have completed the junior year and who have career goals in the health sciences. The program features direct participation in the research activities of senior investigators and an exploration of future employment with the NIDDK. In addition, NIDDK awarded a three year grant to the American Physiological Society (APS) to provide travel fellowships for young minority investigators to the annual fall and spring meetings of the Society.

vi) The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) offers the Minority Investigator Research Enhancement Award (MIREA). These awards provide support for faculty members at minority institutions to allow them to collaborate with principal investigators of active regular research grants funded by the NIAMS. During Fiscal Year 1987, the NIAMS also announced its Minority Travel Award Program (MTAP). Initiated jointly with the National Institute of Diabetes and Digestive and Kidney Diseases, the MTAP is intended to enhance awareness of biomedical research opportunities and to influence more minority students and faculty to become involved in research and research training. Grantees wishing to include travel funds for minority students and/or faculty to attend a national or regional scientific meeting may submit a supplemental grant application for this purpose. Minority students may be from any domestic institution, including the Historically Black Colleges and Universities; faculty members must be from a Historically Black College or University, or from some other predominantly minority institution. During Fiscal Year 1988, NIAMS plans to continue its intramural Summer Student Employment Program. Through this program, high school, undergraduate, and graduate students, as well as college faculty members, are provided summer employment/training opportunities. Special efforts are made to recruit minorities from Historically Black Colleges and Universities and other minority institutions. This exposure of students and faculty provides experience that enhances their ability to become independent investigators and successful applicants for grant support.

vii) In 1985, the National Institute of Dental Research (NIDR) established a Minority Research Supplement Program. This program provides supplemental funds to NIDR-supported principal investigators for the purpose of increasing the number of underrepresented minorities actively pursuing research objectives relevant to the particular funded research project and to the mission of NIDR.

viii) The National Heart, Lung and Blood Institute (NHLBI) offers a Minority Investigator Research Supplement (new in FY 1988) which is designed to attract minority investigators, underrepresented in biomedical or behavioral research, to careers in research related to heart, lung, or blood diseases by providing supplemental funds to ongoing research grants supported by the Institute. Any principal investigator having an active NHLBI research or program project grant, that has a minimum of two years of research support remaining, is eligible to submit a request for an administrative supplement for the purpose of recruiting a minority investigator to participate in the research. This minority investigator must make at least a two year commitment and must spend at least thirty percent of time on research supported by the parent grant.

In addition to this supplemental award, the NHLBI offers the Minority School Faculty Development Award (K14). This program is designed to encourage the development of research careers of investigators who are faculty members at minority schools. Such investigators must provide evidence of interest in and capability to perform modern and sophisticated research in areas relevant to cardiovascular, pulmonary, and hematologic diseases.

It is worth emphasizing that, in addition to the above, all of the Institutes participate in co-funding, with the National Institute of General Medical Sciences, conferences targeted to involve minority scientists in research advances and to stimulate interest in biomedical research and research training. Almost all the Institutes sponsor other annual activities directed toward improving the underrepresentation of minorities in biomedical research. These include recruiting at universities and colleges with large concentrations of minorities, attending meetings and conferences of national scientific and medical organizations targeted toward these groups. Furthermore, the Institutes co-sponsor symposia at annual meetings such as those of The Coalition of Spanish Speaking and Mental Health Organization (COSSMHO), the Society for the Advancement of Chicanos and Native Americans in Science (SACNAS), and the National Institute of Science (NIS).

B. Research Training Activities

1. The Minority Access to Research Careers (MARC) Program of NIGMS was first implemented under the legislative authority of Section 301 of the Public Health Service Act in 1972. Its first component, known as the MARC Faculty Fellowship Program, was a modest undertaking to support faculty members from predominantly minority institutions, to attend major graduate institutions in order to pursue either post-doctoral research training or to complete the requirements for the Ph.D. degree in the biomedical sciences.

A second component, also announced in 1972, is the MARC Visiting Scientist Program. It allows minority institutions to identify prominent scientist-scholars from around the country, who wish to teach and work for periods of time ranging from one academic quarter to one full year at such institutions in order to assist in strengthening research training endeavors and curriculum development related to the biomedical sciences.

In 1975, the MARC Program was established officially as a separate entity within NIGMS. In 1977, the MARC Honors Undergraduate Research Training Program was set up. This program is aimed primarily at strengthening undergraduate science teaching and research training in the biomedically relevant sciences at minority institutions, and at increasing the number of well-prepared minority students who can compete successfully for admission to Ph.D. degree or combined M.D.-Ph.D. degree programs at majority institutions. Under this program, highly qualified minority institutions receive support to provide an enriched curriculum of science courses and specific research training for honors students in the third or fourth year of college. An integral part of this program is the opportunity for the students to participate in a biomedically related research experience at an institution other than their own, particularly a majority institution, or in an industrial setting, during the summer or for a semester away from school. Eligible students are selected on the basis of both their academic achievements and their commitment to subsequently obtain the doctoral degree in an area of biomedical science.

An indication of the success of this program is the high level of demand for MARC trainees. At the annual MARC Scholars Conference, trainees are besieged by recruiters from dozens of major universities. Directors of MARC programs at the 53 institutions having awards report that they are approached with inquiries about their trainees by a large number of graduate schools. There is also a competition for MARC honors students among the many schools and institutions that run summer training programs. Such willingness to invest in the short-term training of MARC Honors Undergraduate Training Program students is seen as a positive reflection of their abilities. In addition, program directors also report that there is a strong interest from the biomedical industrial community in the MARC honors students.

In January 1981, the newest component of the MARC Program, the MARC Predoctoral Fellowship, was announced. This fellowship program, which has grown steadily since its inception, provides support for research training leading to the Ph.D. or M.D.-Ph.D. degree in the biomedical sciences for selected students who are graduates of the MARC Honors Undergraduate Training Program. Awards are conditional upon acceptance into an approved doctoral (Ph.D.) degree or combined degree (M.D.-Ph.D.) program in the biomedical sciences.

Other Institutes that co-fund MARC research training grants with the NIGMS are: The National Cancer Institute, National Heart, Lung and Blood Institute, National Institute on Aging, National Institute of Allergy and Infections Diseases, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Environmental Health Sciences, National Institute of Child Health and Human Development, National Institute of Neurological and

Communicative Disorders and Stroke, and the National Institute of Dental Research. Co-funding from the above Institutes amounted to $460,000 in FY 87. The NIGMS spent $9 million in FY 87 on its MARC Program.

b) As indicated above, although it is not explicitly a research training program, the DRR-MBRS program sponsors student training on its MBRS grants. In addition, DRR sponsors the Minority High School Student Research Apprentice Program. Created in the fall of 1979 by the President's Office of Science and Technology Policy, it was conceived as a government-wide activity. The program was originated to increase the potential pool of minority scientists and engineers in the nation by providing research related work experiences for high school (mostly junior and senior) students during the summer recess. The National Institutes of Health, one of seven agencies asked to participate, initiated a program to provide such students with a meaningful experience in various aspects of health-related research with the expectation that some of these students would decide to pursue careers in biomedical research. Annually, nearly 300 academic institutions (health professional and graduate schools) along with other research institutions throughout the nation receive awards from NIH so as to provide students with these research opportunities. Eligible institutions are those which have received, in the previous year, either a Biomedical Research Support award or a Minority Biomedical Research Support award. Of the 1,000 students in the program each year, more than 90 percent state that they plan to attend college.

c) Each year, the National Institute of Dental Research selects a minority postdoctoral candidate for a one to three year research training assignment in one of its intramural research laboratories. This opportunity is made available through a NRSA Institutional training grant.

d) In 1976, the National Heart, Lung, and Blood Institute announced the Minority Hypertension Research Development Summer Program which was designed to encourage the recruitment and development of minority investigators in specialized areas of research related to prevention, control and education on hypertension. After a successful twelve years, this program is phasing out and will terminate in 1990.

In 1984, the NHLBI announced the Minority Institutional Research Training Program (MIRT). This program is for awards to minority schools and is intended for graduate and health professional students who take a minimum of one year from their professional training to obtain research training, and for postdoctoral trainees who have the potential to develop a meritorious program in cardiovascular, pulmonary, or hematologic research.

3. The Extramural Associates Program

An important effort is the Extramural Associates (EA) Program which is designed to provide practical experience in research administration in order to promote the entry and participation of underrepresented minorities and women in research supported by the NIH. The EA Program is viewed as an investment that will yield multiple benefits -- to participating individuals

and institutions, to the NIH, and ultimately, to the vitality of health-related research in the nation. The objectives of the EA Program coincide with the NIH goals of increasing the pool of research scientists who are minorities and women, and supporting research to address disorders which disproportionately affect these special populations. Among the immediate benefits of the program is the opportunity for NIH staff to work on a collegial basis with academic administrators from the Historically Black Colleges and Universities (HBCUs), and other institutions in which the students are predominantly minority and female. The nominating institution must have a significant proportion of its student enrollment comprised of minorities (Black, Asian, Hispanic, or Native American) or of women, or have otherwise demonstrated a commitment to the assistance and encouragement of such individuals. The NIH selects, for the EA Program, on a competitive basis, scientific faculty and academic administrators from these institutions. Those selected spend five months in residence at the NIH. The desired outcome of the EA Program is that, upon return to the home institution, each NIH-trained associate will assume an active role to promote and expand opportunities for faculty and students to participate in biomedical research.

Table 1 (Appendix B)

NIH TOTAL FUNDING FOR MAJOR MINORITY-TARGETED PROGRAMS

(1973-1988)

Year	Total NIH Budget (Thousands)	MBRS (Thousands)	MARC (Thousands)	Co-Funding 1/ Thousands (MBRS)	RCMI (Thousands)	NHLBI 2/ MHP (Thousands)	NCI 3/ CMBP (Thousands)	Minority Total (Thousands)	Percent of NIH
73	1,762,565	5,000	0	0	0	0	0	5,000	0.284%
75	2,092,897	7,300	0	342	0	0	0	7,642	0.365%
77	2,544,078	9,711	1,788	1,895	0	178	0	13,572	0.533%
79	3,184,976	14,584	2,870	4,300	0	405	0	22,159	0.696%
81	3,569,406	18,857	4,515	5,555	0	591	0	29,518	0.827%
83	4,023,969	19,800	5,975	6,343	0	377	0	32,495	0.808%
85	5,144,650	24,951	7,741	9,537	5,000	673	405	47,902	0.931%
87	6,180,660	28,268	8,566	9,093	10,000	450	836	56,377	0.912%
88	6,666,993	28,520	8,945	9,672	11,010	180	1,625	58,327	0.875%

1/ Additional funding from ADAMHA is not included here.

2/ Minority Hypertension Program

3/ Comprehensive Minority Biomedical Program

TRAINING AND CARKER DEVELOPMENT

I. INTRODUCTION

A. OVERVIEW

Many issues regarding the NIH research training effort were discussed at the regional Advisory Committee meetings. An overriding concern is the level of support for research training. Beyond that, two particularly difficult issues, the effectiveness of clinical training and the increasing cost of tuition payments, are presented for consideration in this report.

Throughout the country, many individuals expressed the strong sentiment that the NIH research training programs were badly underfunded, and that many problems could be ameliorated by a substantial influx of new funds. At each regional meeting it was emphatically stated that more support for NIH training programs was necessary. The testimony indicated all training issues were secondary when compared to the existing level of support. Expressing the sentiment of many, one participant said, "If this nation is to remain competitive world-wide, we need to double our training efforts." Another added that, "the system is not provided with sufficient resources, at every level."

In addition, while numerous people testified about the significant need to train clinical researchers, there was also vigorous and widespread support to maintain and strengthen the basic science training programs. One individual, whose testimony typified many, stated, "It would be a serious oversight not to take advantage of opportunities in modern biology - we must not lose sight of the need to train basic scientists to help us in the year 2000."

Many other people testified about training issues which NIH is already acting upon, such as increasing stipends or improving training in some specialty areas, such as dentistry and nursing. These issues are presented herein only as informational items for the Advisory Committee.

B. HISTORICAL PERSPECTIVE

In the late 50's and early 60's, America went on a research binge. Much of that Federal effort has been attributed to the successful launch of Sputnik by the USSR. In any event, several pieces of legislation were enacted which sharply boosted the Research and Development effort in this country.

However,.the rapid growth in research necessitated a substantial and wide-spread need for science education and research training. Support for medical/dental and health professional education and research training programs flourished under several authorities administered by the Bureau of Health Manpower and various BID's at NIH. For example, in 1968, NIH supported 16,558 trainees including 13,333 institutional trainees and 3225 individual fellowships.

In 1974, the National Research Service Act repealed the numerous existing research training and fellowship authorities and consolidated such authorities in the national research service awards authority. At about the same time, the Bureau of Health Manpower Education was transferred to Health Resources Services Administration. Since enactment of the NRSA legislation in 1974, research training has been within the purview of the NIH, while medical/dental and health professional education has been supported by HRSA.

Since 1976, after a stabilization period of about 2 years, NIH has supported from 10,000 to 11,000 trainees per year; in the last several years, there have been approximately as many postdoctoral as predoctoral trainees.

The NRSA budget for 1988, $235 million, will support 11,086 trainees.

C. EXISTING PROGRAMS FOR TRAINING AND CAREER DEVELOPMENT AT NIH

At the present time, NIH provides research training and manpower development through the National Research Service Award (NRSA) programs, the Research Career programs (RCP), and the Clinical Associate Physician (CAP) program.

NRSA programs support pre- and post-doctoral research training through institutional training grants and individual fellowships. In FY 1988, NIH will support over 2,000 MD post-doctoral trainees on institutional training grants at a cost of approximately $30,000/trainee and will make nearly 600 fellowship awards to MDs/DDSs at a cost of approximately $32,000/trainee. The NRSA programs are administered by the individual Institutes and Divisions, with funding from the NRSA budget.

In addition, the NRSA programs include the Medical Scientist Training Program (MSTP), Short-term Training for Health Professionals, Senior Fellowships, and Minority Access to Research Careers (MARC) programs.

The MSTP is an institutional NRSA training program, also administered by the National Institute of General Medical Sciences (NIGMS), leading to a combined MD/PhD degree. Six to seven years of study and training are required, of which NIH supports six years. MSTP has expanded slowly since its inception, but data indicate most graduates have appointments in clinical departments or are involved in clinical

research. Currently the MSTP budget of $13.9 million supports 719 trainees at a cost of approximately $20,000/trainee/year. There is no corresponding program for dentists.

The short-term training program supports institutional training grants intended to attract individuals into clinical research by providing a brief (3 month) exposure to research to students already committed to clinical careers in health professional schools. In 1988, NIH will provide nearly $2.5 million to support more than 1100 predoctoral trainees and 130 postdoctoral trainees at 76 institutions.

Senior fellowships are individual awards for one year for advanced research training to permit experienced scientists with more than seven years of experience to make major career changes or update their research capabilities. In FY 87, NIH awarded 32 senior fellowships for $0.9 million or approximately $30,000/trainee.

The MARC programs, administered by NIGMS in collaboration with several of the other Institutes, are especially designed programs to attract minority students and faculty into biomedical research. In 1988, NIH will spend $8.7 million to support 480 MARC trainees.

The Research Career Program includes the Research Career Development, Clinical Investigator, Physician Scientist, Dentist Scientist, and other specialty awards. Programs are administered by the individual Institutes and Divisions, with funding from the Other Research budget. In 1988, NIH will make over 1,500 Research Career Program awards for almost $96 million, including approximately 900 awards to MDs and 100 awards to DDSs, at a cost of about $64,000/investigator.

The CAP program provides up to three years of support to either a young physician or dentist to develop research skills at NIH-supported General Clinical Research Centers. At least 80% of the CAP's time and effort are devoted to a clinical research proposal. The CAP program is administered by the Division of Research Resources, with funding from the General Clinical Research Center budget. In 1988, the budget of $3.5 million for the Clinical Associates Program will support 51 MD trainees at a cost of approximately $70,000/trainee.

A large portion of postdoctoral biomedical research training in the U.S. today is supported by NRSA and to a lesser extent, RCP and CAP awards. About one-third of postdoctoral PhDs and about one-half the postdoctoral MDs/DDSs are supported by NIH programs, according to an NSF-NIH Survey of Graduate Science Students. Almost all support for nurses' research training is supported by the NRSA programs.

As noted above, about 11,000 NRSA positions are supported each year, with approximately equal numbers of pre- and post-doctoral positions as either trainees on institutional training grants or as individual fellowships (NIH Data Book). Most predoctoral positions are PhD institutional traineeships.

While the NIH research training programs insure the nation's research enterprise by maintaining the flow of well-trained young scientists into academic and, with increasing frequency, industrial research careers, they also significantly enhance the research environment. Training grants play an important role at an institution as a core program for organizing curricula and engendering cooperation among interdisciplinary faculty.

The NIH training programs are especially important at this time. With the dynamic expansion of biomedical research, there is an increasing need to provide adequately trained manpower to answer the research questions. At the same time, falling enrollments in fields of study related to biomedical science and pressures to pursue lucrative, non-research careers jeopardize the flow of manpower into some fields of biomedical research.

Of particular concern to the NIH is the development of trained investigators for clinical research careers. The ability of medical/dental schools to conduct an effective clinical research program depends on the replenishment of clinical faculty by new entrants who have been exposed to research techniques through formal postdoctoral training. According to a study by the National Academy of Sciences, at present only 25 percent of new faculty members have had any postdoctoral training. The demand for highly trained faculty members will grow as medical/dental schools compete to attract quality students and faculty attrition increases from death and retirement of current faculty.

II. DISCUSSION OF PRINCIPAL ISSUES

A. EFFECTIVENESS OF CLINICAL RESEARCH TRAINING

1. INTRODUCTION

In addition to the regular NRSA institutional and individual awards for pre- and postdoctoral students, NIH provides research training through several other mechanisms, including RCP, CAP, MSTP, and Senior Fellowships. Each of these programs is more costly per individual trained relative to the NRSA individual and institutional awards, but each is also more successful in producing individuals committed to research careers, recognizing that such success is probably largely due to selection biases.

Several studies have confirmed that the more research training and research experience an investigator has, the more successful he or she is in successfully competing for an NIH grant. For example, physicians/dentists who are awarded individual fellowships are more successful grant applicants than physicians/dentists who are appointed as trainees on NRSA institutional training grants, who in turn do better than physicians/dentists who have no NRSA training. In addition, recent data indicates that dentists with a double degree

(DDS/PhD) are more successful in obtaining NIH support than candidates with either degree alone. However, it is also appears true that to increase effectiveness, i.e. the number of people opting for academic or industrial research careers, it costs more per trainee. The most successful trainees are those who have been in research training the longest, or earn awards in more costly training and career development programs.

2. ISSUE

Data suggest that the individual postdoctoral NRSA fellowships, Medical Scientist Training Program, Clinical Associate Physician program and Research Career Programs are more effective than institutional training grants in retaining MD/DDS trainees in research careers. The issue is how to achieve the proper balance among the various programs to maximize the number of individuals, particularly MDs/DDSs, opting for research careers while maintaining an adequate supply of basic scientists.

3. BACKGROUND

At the present time, NIH supports a majority of its training efforts through the NRSA programs, and largely in the form of institutional training grants. The NRSA Act requires 50% to 85% of NRSA funds be awarded for Institutional Training Grants.

In 1984, NIH reported that 53 percent of MDs who are appointed to NRSA institutional training grants receive one year or less of research training and fewer than 20 percent of those ever apply for an NIH Research Grant. However, of those that do apply, success rates are comparable to those of PhDs.

Nevertheless, in spite of the low research grant application rate, the correlation between NRSA institutional training and academic careers has been demonstrated. Forty-five percent of NRSA institutional trainees are on medical school faculties 10 years after their training experience, versus 71 percent for individual fellows. However, only 16 percent of MDs without NIH training are either employed by a medical school faculty or have been awarded an NIH research grant within 10 years.

Compare those data with similar data for PhDs. Eighty percent of PhD institutional trainees are either in research or teaching 8-9 years after obtaining a PhD, versus 90 percent for individual PhD fellows and 60-70 percent of those with no NIH training support.

For MDs/DDSs, evaluation studies have demonstrated that the most effective training programs are those which use a process in which the individual must utilize some initiative in the development of a research design. Thus, individual fellowships and research career

programs are more effective than institutional traineeships or short-term predoctoral training in terms of retaining the MD/DDS trainee in a research career.

Forty-eight percent of the MSTP graduates have been awarded a grant, and 88 percent are in academic or research positions.

Participants in the CAP program represent a more senior cohort than MSTP graduates. Fifty-two percent of the participants in the CAP program have received grant support, and 80 percent have faculty appointments.

The goal of the NIH research training programs is to produce individuals pursuing research as a profession, not as an avocation. The data suggest that more than two years of research training are necessary to assure with a reasonable likelihood that a trainee will be successful in pursuit of a research career. However, many training grant program directors favor the flexibility of allowing more than one person to occupy a trainee slot per year because it allows an opportunity for several individuals to "test the water". In recent years, there has been considerable concern at NIH that some postdoctoral Institutional Training Grants are being used to provide interim support to individuals rather than to provide a serious training experience.

It is possible that NIH could improve the effectiveness of its clinical research training programs by shifting emphasis and resources to individual NRSA fellowships, Research Career, Clinical Associate Physician, and Medical Scientist Training programs. A shift in resources might be more costly per individual, depending upon the stage of training, in which case, fewer trainees, particularly predoctoral, might be supported; however, given the demonstrated success of individual, rather than institutional training, such a shift in emphasis might lead to a more effective process (i.e., a greater percentage of trainees choosing academic research careers).

4. NIH ACTIVITY

In an effort to upgrade the training experience and improve effectiveness, the practice of appointing individuals for periods less than nine months on institutional training grants is being actively discouraged. In addition, more emphasis has been placed on the use of Research Career mechanisms as a means of attracting and retaining MDs/DDSs into research careers.

5. REGIONAL TESTIMONY

Many individuals expressed serious concern about the problem of attracting physicians into research careers. Several problems were

raised, including stipend levels, the length of the training period, and the daunting aspect of competition for NIH research support.

Most suggested that an increase in stipends would help. Several people implied, but would not commit to a recommendation, that without a substantial increase in budget, NIH would be forced to chose between more trainees or higher stipends.

Several individuals suggested emphasizing training opportunities in addition to regular institutional and individual NRSA awards, providing more support for Research Career Programs, the Medical Scientist Training Program, Senior Fellowships, and the FIRST award.

Some expressed the opinion that the physician scientist award, or a similar mechanism which would combine a strong grounding in basic science with clinical research, provides the most likely method for assuring developing productive young faculty. A few individuals even suggested that NIH develop a quota of awards, with set-aside funds, for young investigators, including Research Career Program awards and FIRST awards.

A few individuals expressed a need for sabbatical-like research training experience for young faculty just prior to their review for tenure.

On the other hand, the American Society of Microbiologists cautioned that if the number of trainees falls below the minimal number recommended by the National Academy of Sciences, the country will not be able to maintain an adequate cadre of well-trained biomedical scientists.

6. OPTIONS FOR THE ADVISORY COMMITTEE TO THE DIRECTOR

The Advisory Committee is asked to consider whether the need to improve the effectiveness of clinical research training programs in attracting clinicians to research careers is great enough to warrant major shifts in training program emphasis.

Research Career Programs are funded from the Other Research line of the NIH appropriation; NRSA programs are funded under separate authority. Increased support for the Research Career Programs therefore would reduce the research grant budget but would not necessarily affect NRSA programs. However, the NRSA budget has limited flexibility at present. Any shift of resources into one NRSA program would likely come at the expense of another NRSA program.

B. TUITION

1. INTRODUCTION

In FY 88, the NIH will provide approximately $43 million per year in tuition for trainees in both state and private institutions. Graduate tuition has been increasing at an average rate of 11 percent per year. With the NRSA appropriation essentially level and tuition on the upswing, it is apparent from several projections that the NIH and the academic community could face continued reductions in the number of trainees that can be supported and thereby result in a decreasing pool of qualified biomedical scientists.

2. ISSUE

The issue is whether NIH should implement a cost-containment policy on tuition payments on NRSA training awards.

3. BACKGROUND

Since the inception of its training grant program, the NIH has generally paid full costs for tuition and related fees. In 1984, however, the NIH convened a group of representatives from large and small, public and private universities to consider the rising costs of graduate education. Based on the IOM recommendations regarding the number of trainees to be maintained, that group recommended that tuition on training awards should be honored at the requested levels for the first year, and that future incremental requests be restricted to six percent per year.

This new policy produced some reductions in tuition payments, but tuition payment requests continued to increase on noncompeting training grants and were not controlled at all on competing grants. Payment of large tuition increases with no corresponding NIH budget increases for research training has resulted in a steady decline in the number of trainees supported over the past decade. For example, limitations in funding have forced the NIGMS, which provides about two-thirds of all NIH predoctoral biomedical research training support, to reduce the number of its predoctoral training positions from 4,000 in 1972 to 1,600 in 1986. This was necessitated in large part by an annual increase in tuition payments which from 1977 to 1985 rose on an average from $2,700 to $6,240.

This reduction in the number of NIH trainees has resulted both in fewer institutions receiving training grant awards and in the reduction in the number of trainees supported by most training grants.

4. NIH ACTIVITY

In July 1987, the NIH convened another workshop to discuss tuition cost containment. Participants in this workshop recognized that recent sharp increases in tuition were threatening to precipitate an acute crisis. Further significant reductions in predoctoral training positions could be avoided only by a substantial budget increase. However, the workshop proposed as a temporary solution, a cap on tuition reimbursement and a freeze on tuition reimbursement at 90 percent of the 1987 level.

The temporary cap on tuition reimbursement was never imposed in a uniform fashion across all the NIH components, however. The institute affected most by tuition increases, NIGMS, has imposed a freeze sporadically on a year by year basis.

A separate, internal NIH committee on payment of tuition has recommended the award of a two-tiered flat tuition and fee allowance in lieu of payment of full tuition fees. The two levels of the tuition fee allowance could be set below, at, or above the current average tuition payments on training grants for each of the two types of institutions: public and private. Establishment of a lower tuition and fee allowance would lead to substantial cost savings that could be utilized for the support of many additional trainees.

5. REGIONAL TESTIMONY

Concern was expressed at two regional meetings that there would be a crisis in manpower training without some cost containment and without a substantial increase in the training budget. The American Society of Microbiologists supported the recommendations of the NIH Committee for a two-tiered tuition and fee allowance.

6. OPTIONS FOR THE ADVISORY COMMITTEE TO THE DIRECTOR

Several options are available for consideration in the area of tuition cost containment. The long-standing NIH policy of payment of full tuition on research training grants could be reinstituted;

The temporary cap on tuition and freeze on tuition increases could be adopted as permanent policy;

The two-tiered tuition fee allowance proposed by the NIH committee on tuition cost containment could be implemented as NIH policy;

More severe limitations on payment of tuition could be considered.

C. THE NEED FOR RESEARCH TRAINING

1. ISSUE

As noted above, the purpose of the NRSA and Research Career Programs is to provide the nation with an adequate number of biomedical investigators to assure continued scientific progress. To achieve this purpose, these programs must maintain a balance between the expanding frontiers of science, changes in the biomedical scientist population, and fiscal constraints. The issue then is to define the proper training effort, given the budget constraints existing now and in the near future, appropriate to meet the expanding needs of science as well as attrition within the scientist population.

2. BACKGROUND

Since the inception of the NRSA programs in 1974, the size and nature of the manpower pool required to meet the national need for biomedical investigation has traditionally been estimated in biennial reports prepared for NIH by the Institute of Medicine (IOM) of the National Academy of Sciences. In preparing these estimates, the IOM considers scientific progress, medical/dental and graduate school enrollments, attrition within the biomedical science community, and to some extent, societal trends which may affect manpower needs. The IOM report also examines in depth the research manpower specialty needs of dentistry and nursing, and other special areas such as biotechnology and molecular biology. The IOM estimates provide the basis for budgetary requests and appropriation decisions.

Since the early 1970's, training funds have declined sharply relative to the total budget. The most recent (1985) IOM report assessed the suitability of existing programs to meet the identified needs. The NAS has found that, after adjustment for inflation, training funds have declined by almost 6 percent per year since 1971, while at the same time, expenditures for research have increased by 3 percent per year. Nevertheless, the NIH has been able to maintain a relatively stable number of trainees. This has been accomplished by restricting stipends to what are now unrealistically low levels and, in some cases, restricting increases in tuition payments. It is unlikely that with the expanding need alluded to above, NIH will be able to continue to maintain this stable flow of investigators without increased appropriations.

3. NIH ACTIVITY

At the present time, the workscope for the next IOM report (now on a quadrennial basis) is being prepared. In addition to the analyses

presented in previous reports, there will be some consideration for measurement of success of the training programs.

4. REGIONAL TESTIMONY

Several individuals testified regarding the need and importance of the NIH training programs. In addition, a number expressed deep concerns that the supply of new researchers in biomedical sciences is in serious jeopardy for a variety of reasons.

There was testimony that in the next ten years, a large percentage of academicians will be retiring and that the workforce needed to replace them must be put in place in an orderly manner. There was also discussion of a physician surplus, but testimony stressed the long-term need for training. "In ten years, we'll be sorry we were reticent to allocate resources now. We are in a transition period right now." However, at several regional meetings, people recognized that economic forces are working against recruitment of more trainees into research careers.

In spite of data to the contrary, there was testimony that a major deterrent to pursuit of a research career is the daunting prospect of competition for research funding for individual investigators.

Others testified that the supply of clinician researchers is a particularly crucial problem not only for the same reason, but also because of the economic pressures forcing debt-laden clinicians away from further training.

Several individuals commented on the general importance of training in specialty areas, such as nursing, dentistry, obstetrics-gynecology, thrombosis, integrative biology, transfusion medicine and otolaryngology.

D. STIPENDS

1. ISSUE

An upward adjustment in stipends may be necessary in order to continue to attract highly qualified candidates, especially those holding the MD degree, into NRSA biomedical and behavioral research training programs and Research Career Programs.

2. BACKGROUND

Trainees and fellows on NRSA training grants and fellowships currently receive a stipend. Some training grants also provide allowances for tuition and other expenses. These stipends may be supplemented with

non-federal funds. However, stipends are now considered taxable income under the provisions of the 1986 Tax Reform Act.

The stipend for predoctoral NRSA trainees is currently $6,552 per year; the stipend for postdoctoral NRSA fellows currently ranges from $15,996 to $30,000 per year. Research Career Program awardees receive salary support up to $40,000.

A critical need still exists to assure that an adequate number of physicians receive the proper training to enter research careers. While the decline in numbers of physicians seeking research careers has been arrested, there is no assurance that it has been reversed. There are a number of reasons for this paucity of physicians seeking research training, but there is little doubt that the lack of a competitive stipend continues to be a contributory factor. The average clinical research fellow normally enters a research training program two years after receiving a professional degree. According to the 1987-88 figures from the Council of Teaching Hospitals of the Association of American Medical Colleges, the mean house staff stipend nationwide for a person so trained is $25,056. A comparable research training fellowship offered under the NRSA is $21,996. A recently completed review of current stipends reveals that comparable awards from other granting agencies are substantially higher than the NRSA.

The IRS tax changes now make both pre- and postdoctoral stipends fully taxable. Prior to 1987, predoctoral stipends were fully tax exempt and postdoctoral stipends were tax exempt at the rate of $300 per month not to exceed 36 months in a lifetime. This change in tax law places a substantial new financial burden on NRSA trainees.

3. NIH ACTIVITY

The NIH Director, with the support of the Institute Directors, recently approved stipend increases for both predoctoral trainees (from $6,552 to $8,500 per year) and postdoctoral fellows (from a range of $15,996 to $30,000 increased to a range from $17,000 to $31,500 per year).

The proposed increase in predoctoral stipends will place NIH supported predoctoral trainees in a more equitable relation to those supported by other Federal agencies.

The proposed postdoctoral stipend increase will eliminate the differential between what is available for a house staff officer and a physician postdoctoral trainee.

4. REGIONAL TESTIMONY

The professional biomedical and behavioral research community, as individuals, through their congressional representatives, professional societies and as members of scientific review groups and of the NIH National Advisory Councils, have expressed concern that qualified candidates for research careers are being discouraged in the pursuit of those careers by the lack of adequate stipends available for NRSA research trainees and fellows. Furthermore, there is concern about the increasing gap between what a physician/dentist can earn as a house staff officer in clinical training and the stipend offered for research training, a problem which is compounded by the level of debt incurred by medical/dental students at the time of graduation.

There was testimony to the effect that potential physician investigators now emerge from medical/dental school with staggering debts. To attract such individuals into research paths requires that they extend their indebtedness for an additional period, during which their fiscal status may actually deteriorate. "NIH support mechanisms are unrealistic - they mandate either further debt accumulation or income-generating activities which defeat the purpose of training."

A large number of individuals at regional meetings expressed the need for either more numbers of trainees, larger stipends, or both. However, the most emphatic recommendations were that stipends should be raised. Adjectival comments about the existing stipend level, especially for pre-doctoral students, ranged from inequitable to ridiculous. The general sentiment was that many of the people who might be competing for research training are already heavily in debt; any further delay in their career and income production is too much of a sacrifice. Several people expressed concern that MDs/DDSs in particular are thus discouraged from pursuing research careers.

However, one individual testified that the current stipend structure acts..."as a filter, through which only the most motivated pass through. However, at present the conditions are such that the test is counterproductive. The stipends have to be adjusted to a reasonable level."

Data presented by the AAMC indicate that indebtedness may also be a problem in attracting basic scientists into research training. The average PhD now graduates with $7,000 in debt, versus $30,000 for an MD. There was testimony that this level of indebtedness is a comparable fraction of either the MD's or PhD's annual income, and therefore is of no less significance for the PhD considering a research career.

D. DENTAL RESEARCH TRAINING

1. ISSUE

The 1985 Report of the Committee on National Needs for Biomedical and Behavioral Research Personnel published by the Institute of Medicine recommended a gradual increase in the number of training positions supporting dentists under the NRSA mechanism from a level of about 100 in 1984 to 320 in 1990. There have been no substantive changes in the appropriations for the NIDR training programs in the last three years and the appropriation for FY 89 is expected to be in the same range. At this level, the NIDR will not be able to implement even the first step of the increase recommended in the IOM Report.

2. BACKGROUND

In January 1987, the Director of the National Institute of Dental Research appointed an ad hoc consultant panel and charged them to evaluate the Institute's National Research Service Award program, and, if indicated, to make specific recommendations for program improvement.

The panel was asked to consider a number of issues of concern to the NIDR in regard to its NRSA program. A major concern is the decline in the number of dentists supported for postdoctoral research training that has occurred over the last decade. In 1970, 238 dentists were preparing for research careers with NIDR training support. By FY 1980, the number of dentists receiving similar support had declined to only 49 individuals.

3. NIH ACTIVITY

The ad hoc consultant panel of the NIDR developed 14 recommendations for improvement in the research training programs of the NIDR. Many of the recommended improvements can be accomplished within existing policy guidelines.

The major recommendations of the panel include: make the institutional training grants five year programs for dentists leading to a Ph.D., degree; establish a new mechanism for initial support of recently graduated dentists to obtain further research training; initiate an annual receipt date and review cycle for all competitive institutional training grant applications; and triple the number of trainees supported by the institute.

The panel recommended a threefold increase in the number of trainees supported by the Institute. It is unlikely this can be accomplished in the absence of an overall increase in the NRSA appropriation.

The panel recommended establishment of a new mechanism which would bridge the first clinical degree and an individual fellowship award. NIH considers the institutional training grant to be suitable for such purposes and therefore has not moved to implement this recommendation.

4. REGIONAL TESTIMONY

Several dental researchers testified on behalf of support for dental research training. Particularly strong support was expressed for the Dentist/Scientist award (an award comparable to the Physician Scientist Award in the Career Development Program), the recommendations of the NIDR ad hoc Panel on Training, and recommendations of the IOM Personnel Needs Report.

Several people supported the dentist/scientist award. It was pointed out that the American Association of Dental Schools recommended that the steady-state goal of 25 dentist-scientist graduates per year be maintained.

It was suggested that the period of support for postdoctoral awards for dentists and clinicians in general be increased from three to five years.

There was testimony that there should be a significant increase in the NRSA stipend level and a coordinated cycle for training applications with decisions for funding made in a more timely manner.

There was strong and widespread support for the NIDR consultant panel recommendations. "The AADR enthusiastically supports these recommendations" In addition, there was considerable support for increased flexibility in funding newly graduated dentists who wish to pursue research training. "This could be achieved by making monies available to the schools to support the new graduate during a one year incubation period in which he/she was gathering preliminary data and writing a fellowship proposal. Such monies could be awarded similar to BRSG support..."

E. NURSING RESEARCH TRAINING

1. INTRODUCTION

Nursing research is a rapidly developing area. In its attention to interventions, procedures and methods for patient care, nursing research complements both basic and clinical biomedical research. There is an increasing demand for nurse faculty with research training and a growing pool of fellowship applicants for nursing research training.

2. ISSUE

Program capacity and levels of support for nursing research training should be expanded. There is a need to increase the total number of nurses in research training as well as increase those in postdoctoral study.

3. BACKGROUND

The number of nurses engaged in research has been growing at an exponential rate for the last ten years. The number of doctoral programs in nursing has been rising at a similar rate over the same period. Fewer than one percent of nurses with doctorates are unemployed. These factors, the increased growth, and the low unemployment, indicate a growing need for support for nursing research training. NRSA fellowships and traineeships constitute one of the principal sources of support for nurses pursuing research training. The IOM Personnel Needs Study recommended doubling the number of nursing research trainees to 320 by 1990. The IOM study also recommends postdoctoral awards should be at least 15 percent of the total number supported. In FY 1987, 8 percent were postdoctoral awards.

4. REGIONAL TESTIMONY

Several eminent nurse researchers testified at the regional meetings that there was a growing need for support for nursing research training. However, the general approach of these individuals was to support increases in the total NRSA program, rather than to argue for increases in the Nursing Center budget alone.

5. NIH ACTIVITY

The National Center for Nursing Research (NCNR) FY 1988 appropriation is nearly 17 percent greater than for FY 1987. In FY 1988, NCNR will support 132 individual fellows and 59 institutional trainees, for a total of 191 trainees compared to 167 trainees in FY 1987. Although the President's budget request for 1989 represents an 8 percent increase for the NCNR, funding of the nursing research training programs would remain constant.

III. CONCLUSION

The Advisory Committee to the Director is asked to consider the NIH research training policies in two separate but not unrelated areas: program balance and tuition containment.

The first issue is whether the need for greater effectiveness in the training of MD researchers is compelling enough to warrant a shift of training resources into programs for such training which have higher success rates. Any such shift would result in fewer trainees, most likely at the predoctoral level. The ramifications of any change in policy which would produce fewer trainees must be considered.

The second issue is the advisability of developing a policy of tuition containment on NRSA research training grants. Such a policy would provide NIH more flexibility in terms of the number of trainees that could be supported, but obviously would place more burden on institutions participating in training programs. The Committee is asked to consider what impact such a policy would have on the NIH research training programs.

NATIONAL RESEARCH SERVICE AWARD MECHANISMS

Institutional Awards

Institutional Research Training Grants

Medical Scientist Training Program

Short-Term Training Programs

MARC Honors Undergraduate Program

Individual Awards

Individual Fellowship

Senior Fellowship

MARC Predoctoral Fellowship

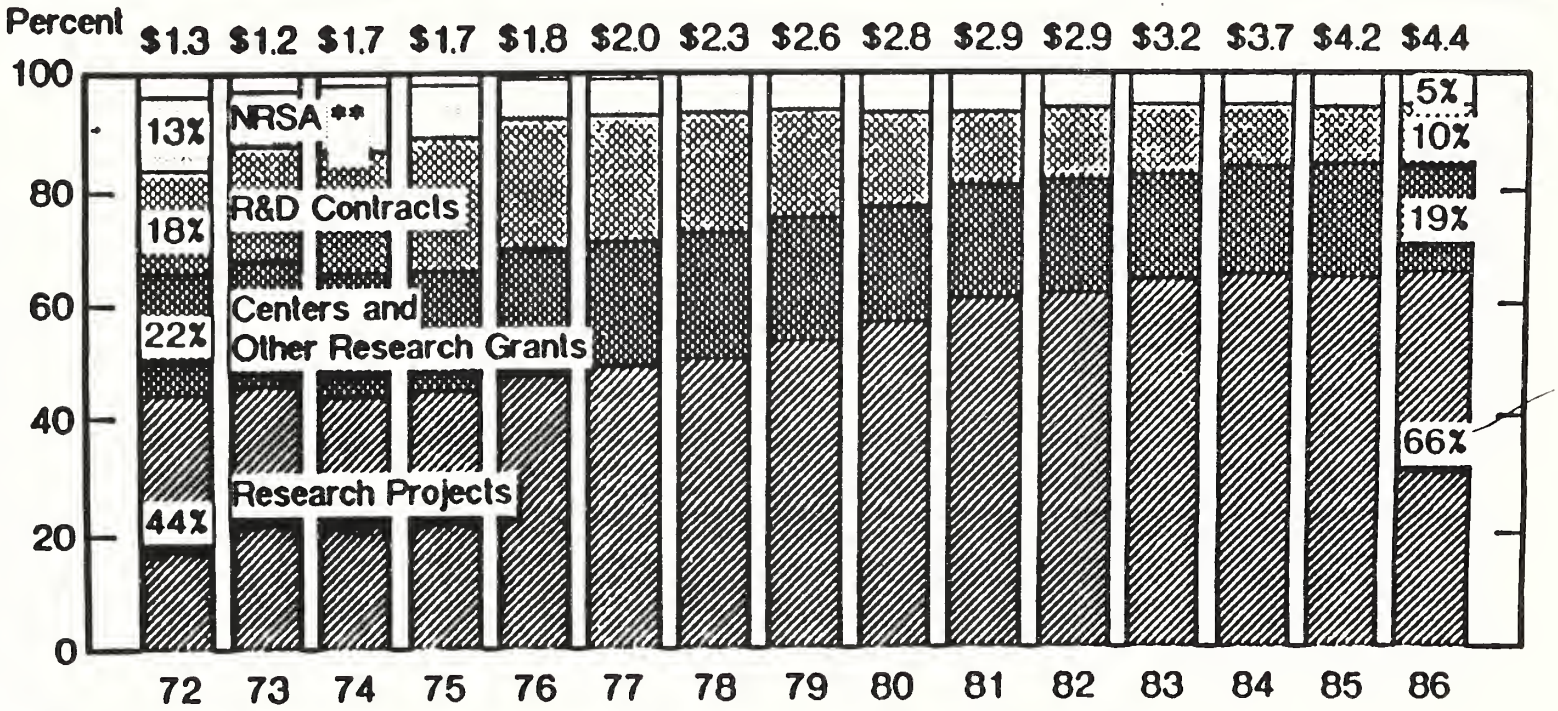
MARC Faculty Fellowship

RESEARCH CAREER DEVELOPMENT AWARDS

RCDA	Research Career Development Award (K04)
CIA	Clinical Investigator Award (K08)
PSA	Physician Scientist Award (K11, K12)
DSA	Dental Scientist Award (K15, K16)

Allocation of NIH Extramural Awards by Activity, FY 1972-1986 Percent of Amount Awarded

(Current Dollars in Billions)



Note: Excludes TQ.* Includes Construction and Medical Library Grants. ** Includes Pre-NRSA Training.
Source: NIH, DRG, Statistics and Analysis Branch

NIH SUPPORTED TRAINEES AND FELLOWS

Year	Dollar Obligations (in thousands)	Full-Time Training Positions	
1974	$186,489	13,341	Impoundment Release NRSA Act
1975	154,875	12,272	Stipend Increase
1976	119,998	9,654	
1977	127,458	10,198	
1978	143,926	11,123	
1979	143,661	11,197	
1980	176,388	10,664	Stipend Increase
1981	175,172	10,695	
1982	150,474	10,406	Allowance Cut
1983	164,654	10,570	Stipend Increase
1984	166,462	10,514	
1985	217,467	10,370	Stipend Increase
1986	212,780	10,382	
1987	232,577	11,175	
1988*	235,247	11,086	
1989** P.B.	247,227	11,336	

* Estimate
** Includes 5,275 for 250 AIDS trainees
P.B. President's Budget

RESEARCH CAREER DEVELOPMENT AWARDS

Year	Dollar Obligations (in thousands)	Number of Awards	
1979	$ 48,924	1,339	
1980	49,506	1,344	
1981	50,492	1,252	
1982	50,736	1,236	
1983	50,284	1,187	
1984	53,645	1,208	Salary Ceiling Raised
1985	76,231	1,344	
1986	80,014	1,335	
1987	89,045	1,422	
1988*	95,918	1,510	

* Estimate

TRAINING AND CAREER DEVELOPMENT

	Percent of NIH Budget	
	Research Training	Career Development
1980	5.1	1.44
1981	4.9	1.41
1982	4.3	1.39
1983	4.2	1.24
1984	4.1	1.19
1985	4.3	1.48
1986	4.1	1.45
1987	3.7	1.44
1988*	3.6	1.35

*Estimate

NRSA PROGRAM DISTRIBUTION
as a
PERCENT OF FUNDS

	1977	1980	1983	1986	1989
Funding (in thousands)	$127,458	$176,388	$164,654	$212,780	$245,690
Special Programs*	6%	9%	11%	11%	11%
Predoctoral	34%	22%	26%	24%	27%
Postdoctoral	60%	69%	63%	65%	62%

*MARC, MSTP, Short-Term Training

NRSA PROGRAM DISTRIBUTION
as a
PERCENTAGE OF POSITIONS

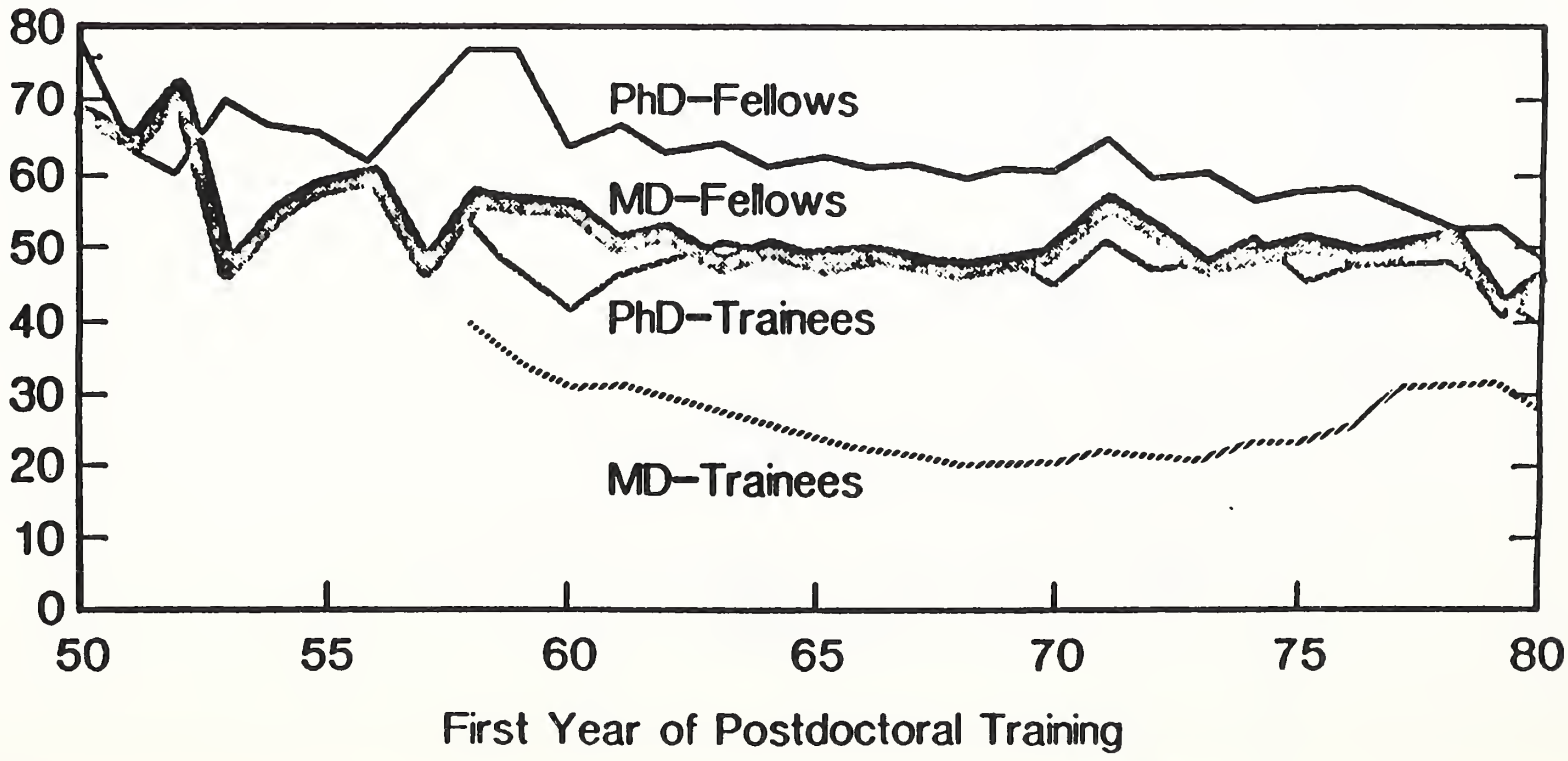
	1977	1980	1983	1986	1989
Positions	10,198	10,664	10,570	10,382	11,350
Predoctoral	44%	37%	36%	34%	37%
Postdoctoral	50%	52%	50%	52%	50%
Special Programs	6%	11%	14%	14%	13%
MARC	(1.3%)	(3/0%)	(4.6%)	(4.6%)	(4.2%)
MSTP	(4.9%)	(6.2%)	(6.4%)	(6.8%)	(6.3%)
SST:SHPS		(2.0%)	(2.8%)	(2.6%)	(2.4%)

TRAINING AND CAREER DEVELOPMENT

ISSUE: The Effectiveness of Clinical Research Training

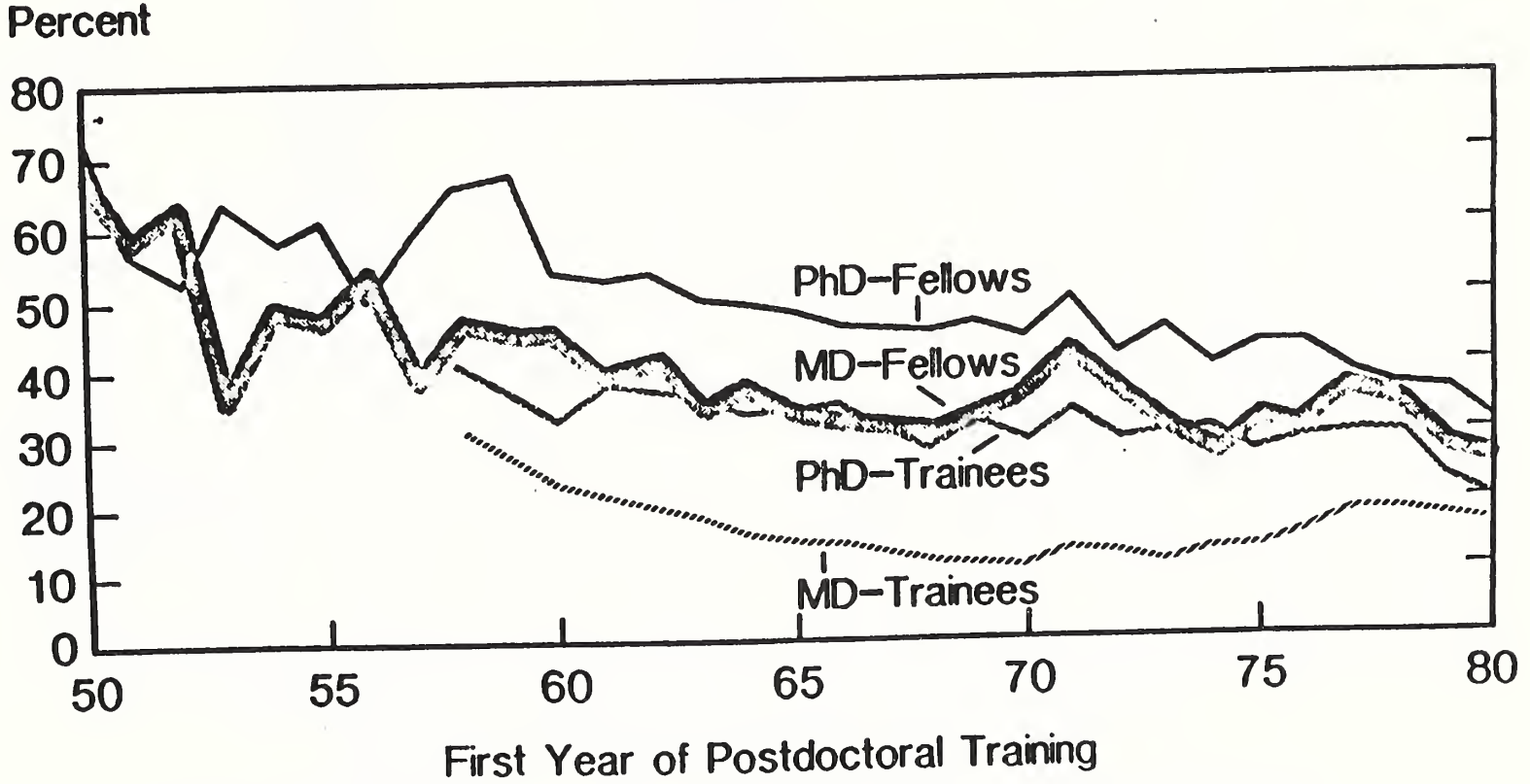
Percentage of NIH-Supported Postdoctorals Becoming NIH Grant Applicants,

Fellows and Trainees, MDs and PhDs



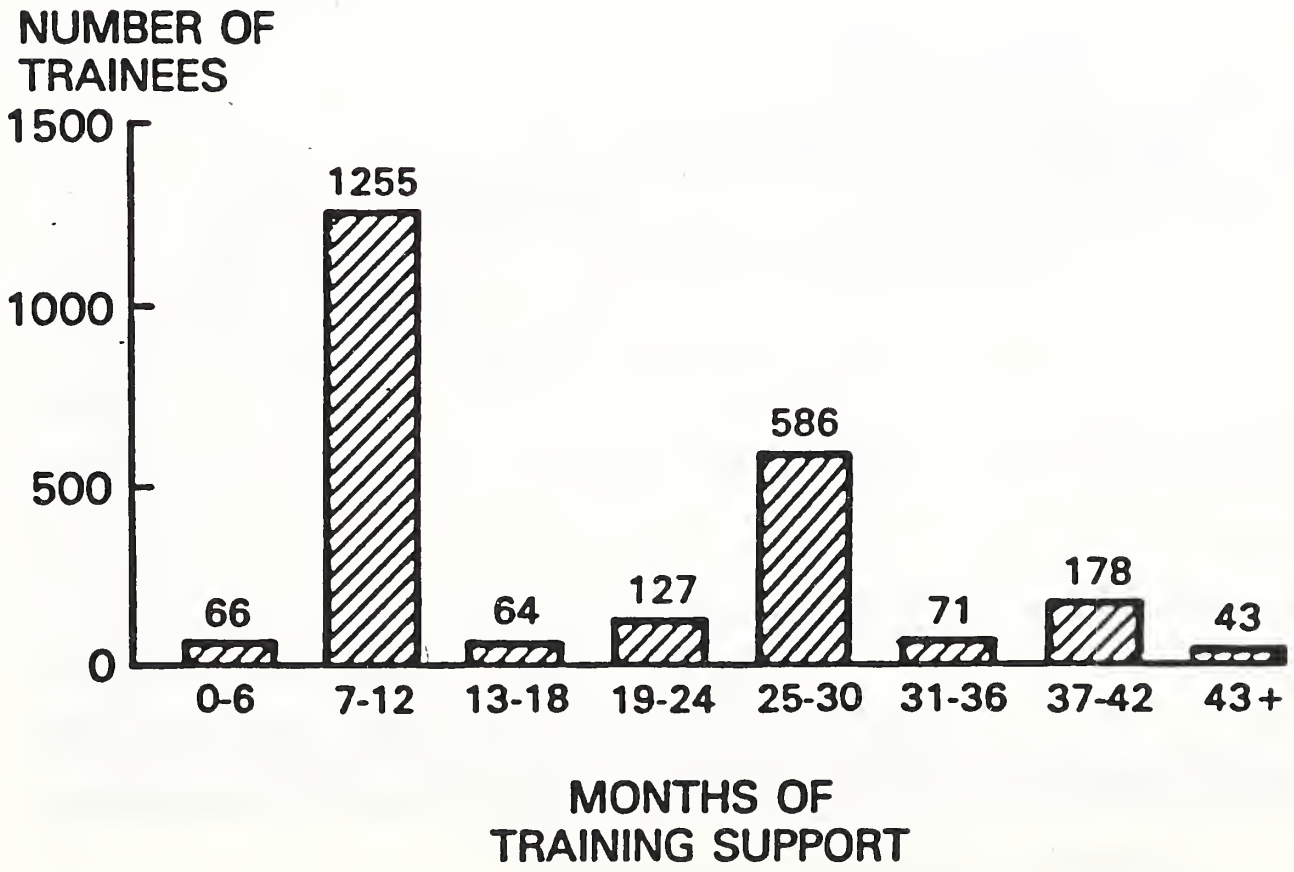
Percentage of NIH-Supported Postdoctorals Becoming NIH Grant Recipients,

Fellows and Trainees, MDs and PhDs



HOW LONG IS A T32 TRAINING EXPERIENCE?

NUMBER OF NIH T32 M.D. TRAINEES BY MONTHS OF SUPPORT (T32 GRANT ONLY) BEFORE BEGINNING "PAYBACK," JAN. 1981 - MAR. 1984



Source: PEB/DPA/OPPE/NIH, 5/84.

CAREER OUTCOMES FOR
MDs WITH NRSA TRAINING

	Without NIH Training	Institutional Trainees	Individual Fellows
% Awarded NIH Grant	0.6	7.1	20.0
% Employed by Medical School	15.6	44.9	68.8

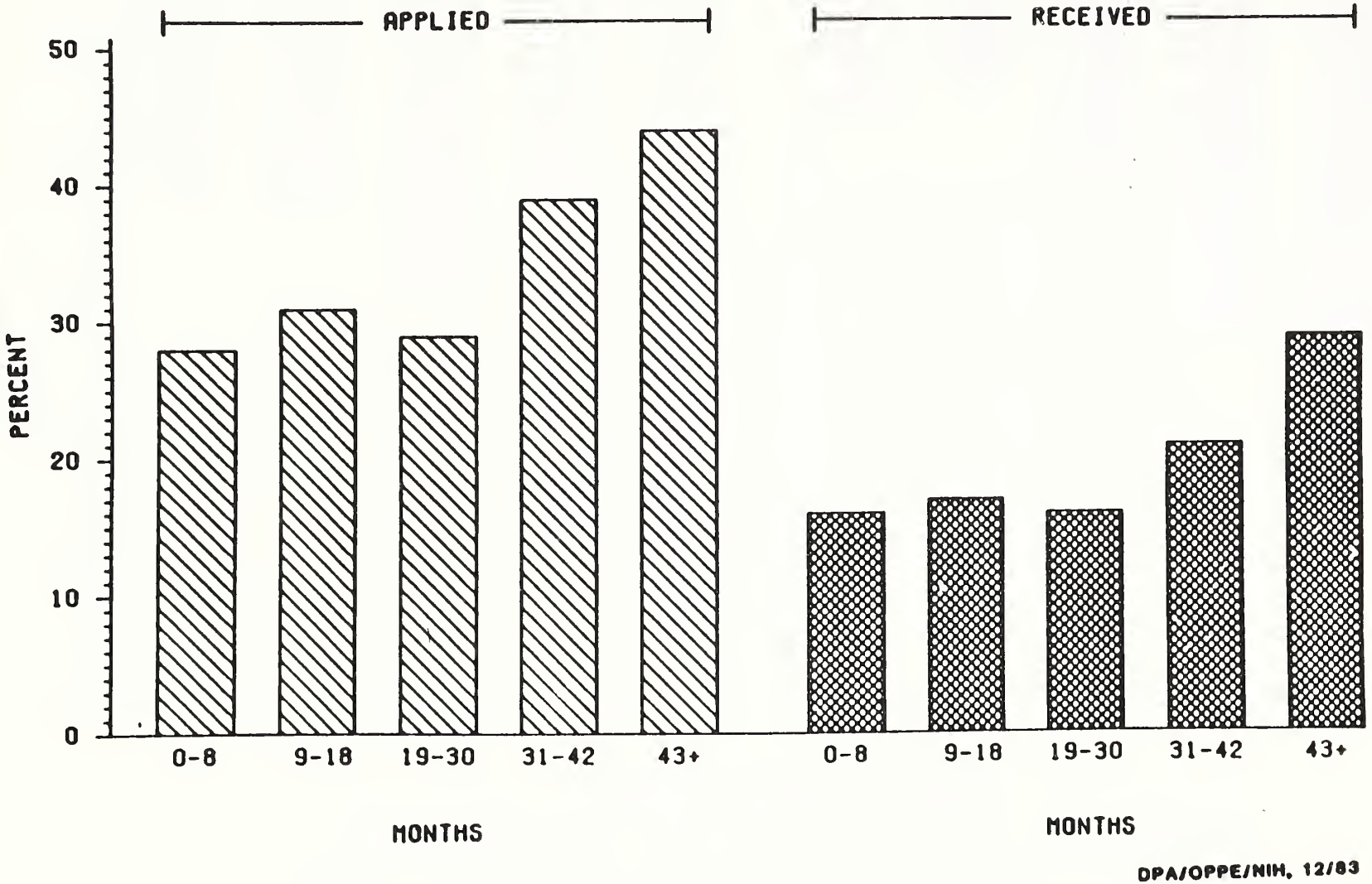
Source: PEB/DRPA/OPPE/NIH, 6/84

CAREER OUTCOMES FOR
PH.D.s WITH NRSA TRAINING

	Without NIH Training	Institutional Trainees	Individual Fellows
% Awarded NIH Grants	9.9	24.5	37.8
% in Academic Positions	53.5	55.9	68.8
% in Research Positions	61.9	78.7	90.4

PERCENTAGE OF PHD POSTDOCTORAL TRAINEES WHO APPLIED FOR OR RECEIVED A GRANT, BY LENGTH OF SUPPORTED TRAINING

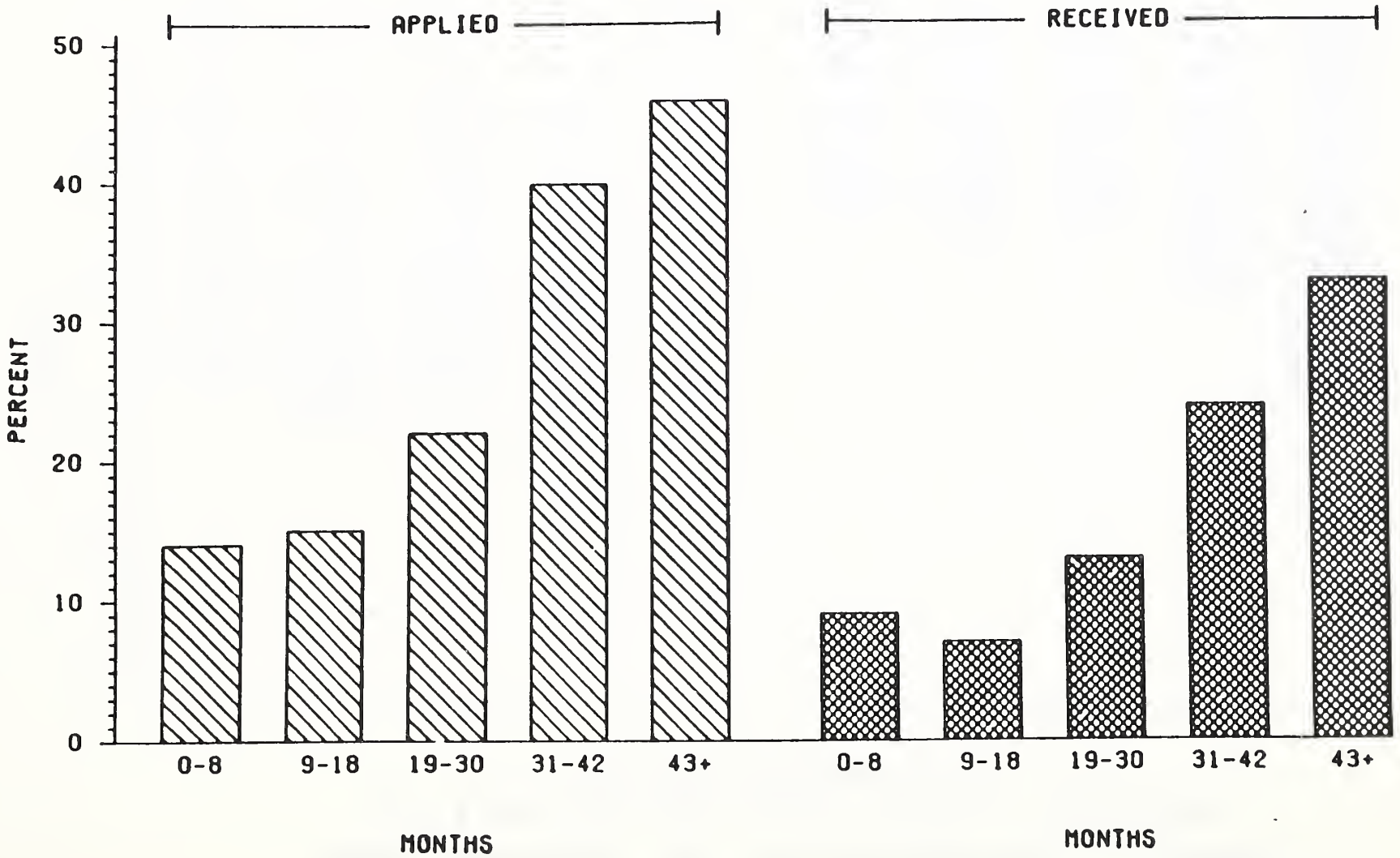
FIRST YEAR OF TRAINING 1976-80



DPA/OPPE/NIH, 12/83

PERCENTAGE OF M. POSTDOCTORAL TRAINEE. WHO APPLIED FOR OR RECEIVED A GRANT, BY LENGTH OF SUPPORTED TRAINING

FIRST YEAR OF TRAINING 1976–80



DPA/OPPE/NIH, 12/83

TRAINING AND CAREER DEVELOPMENT

ISSUE: Increasing Costs of Tuition in Research Training and Programs

TUITION COSTS

	Predoctoral Trainees	Tuition ($ in thousands)	$/Trainee
1982	5,055	27,944	5,538
1983	5,220	31,836	6,099
1984	5,097	33,963	6,663
1985	4,911	39,070	7,956
1986	4,807	40,588	8,391
1987	5,242	42,639	8,134

TUITION OPTIONS

- Full Payment
- Tuition CAP with Freeze
- Two-Tiered Tuition Fee Allowance
- Partial Payment

TRAINING AND CAREER DEVELOPMENT

ISSUE: **The need for Research Training**

NAS/IOM RECOMMENDATIONS
(Number of FTTP's)

	Recommended	Actual
1982	10,740	10,406
1983	10,750	10,570
1984	10,760	10,514
1985	10,770	10,624
1986	10,813	10,382
1987	11,037	11,175
1988	11,037	11,086*
1989	11,436	11,350
1990	12,103	--

*Estimate

TRAINING AND CAREER DEVELOPMENT

ISSUE: An Upward Adjustment in Stipends May be Necessary

PREDOCTORAL SUPPORT, 1986

Agency	Stipend (per year)
USDA	$15,000
Office of Naval Research	13,260
NSF	12,300
HHMI	12,300
NASA	12,000
Department of Defense	12,000
Department of Energy	12,000
NIH	6,500

POSTDOCTORAL SUPPORT

Agency	Stipends (per year)
VA	35,000
DOE	35,000
NBS	32,000
Ford FND	26,350
NIH	24,000
NSF	21,600

NRSA POSTDOCTORAL STIPENDS
COMPARED WITH
HOUSESTAFF SALARIES

Years of Relevant Experience	NRSA Stipend FY 1987	Mean Housestaff Salary 1987-1988
0	$ 15,996	$ 22,747
1	17,004	23,844
2	21,996	25,056
3	23,004	26,340
4	24,000	27,525
5	26,004	28,753
6	27,996	--
7 or more	30,000	--

POSTDOCTORAL STIPEND

Years Postdoctoral	Current Stipend	Proposed Stipend
0	$15,996	$17,000
1	17,004	18,000
2	21,996	25,000
3	23,004	26,250
4	24,000	27,500
5	26,004	28,750
6	27,996	30,000
7 or more	30,000	31,500

TRAINING AND CAREER DEVELOPMENT

ISSUE: Support for Research Training for Dentist and Nurse Scientists

Conclusions

- The most overriding concern is the low level of support for research training programs. All other problems are of secondary importance.

- The effectiveness of NIH training and research center programs might be increased by a shift in emphasis and resources, but consideration must be afforded programs which would be adversely affected by such shifts.

- Without increases in budget, an NIH-wide policy or tuition containment should be considered.

- A further increase in stipends may be warranted.

- The importance of research training programs for specialties such as dentistry and nursing should be recognized.